EXHIBIT 11

Testing of the EMG and ACG sensors with technical explanations produced on 04/30/2009

When a person is relaxed, the EMG level is so low, that it makes no difference if you have 3 ECG electrodes or four balanced EMG electrodes, because the level of EMG on the palms of the hands during relaxation is about 20 to 50 microvolt.

The range of EMG according to biomedical signals standards (reference is the Book "Introduction To Biomedical Electronics" by E.J Buksttein, page 18) are:
ECG amplitude is ranging between 500 to 5000 microvolt and EMG amplitude is between 20 to 5000 microvolt.

Please note that 1000 microvolt is 1 mv (millivolt). (1mv is equal to 0.001 volt).
(1 microvolt is one millions part of the volt).

"R" wave on the palms of the hands on average is 200 to 1500 microvolt, which depends on the size of a heart and position of a heart in chest cavity (which is called polarization of a heart). It is mentioned in the summery of my declaration.

In these tests we will be measuring EMG on the palms of the hands with EMG monitor at the output of a differential amplifier. These measurements will be done in the same frequency band as "R"wave of ECG, which is from 15 to 20 HZ.

The advantage of Biosig EMG/ECG technology is that it reduces EMG level monitored on the palms of the hands without reducing "R"wave level of ECG. This increases ECG signal to EMG noise ratio and makes a heart rate monitor to perform accurately on exercise machines.

When you hold an elongated member steady the level of EMG rises, but still enables ECG "R" wave to be recognized, even with 3 ECG sensors or 4 non- balanced sensors, which represent 3 ECG sensors in relationship to a heart, as I have described in my declaration.

Please take a look at the experiments shown on the next pages.
These experiments were produced and witnessed in the past by many people.

But the experiments shown bellow on 04/30/2009 were prepared, witnessed and photographed by myself and technical personal of Biosig.

Pic. 1

This picture shows 4 electrodes, which are non- balanced sensors connected to an EMG monitor, called "Electronic Gym" The spaces between left and right electrodes are different, as could be seen. Two middle electrodes are indifferent and two side electrodes are potential. Sensors are not touched. The reading of the monitor is 0.

Pic. 2

This picture shows the action of non-relaxed, but **Holding** normally of 4 non- balanced sensors. EMG reading on the EMG monitor is 450 microvolt.

Please note that we are measuring the level of EMG signal at the output of differential amplifier, which is connected to two potential electrodes and two indifferent electrodes, which are connected to a ground.

Pic. 3

This picture shows the action of non-relaxed, but Holding normally 3 sensors, without touching the fourth sensor. EMG reading of the monitor is 400 microvolt . This is less than holding 4 non-balanced sensors.

Conclusion the 3 ECG sensors works better than 4 non- balanced electrodes ECG sensor.

Pic. 4

This picture shows **Grasping of** 3 sensors only, without touching the fourth sensor. EMG reading is 550 microvolt .

Pic. 5

This picture shows **Grasping** of 4 non-balanced sensors. EMG reading of the EMG monitor is **1150 microvolt.**
It is clearly demonstrates that 3 sensor ECG system is better rejecting EMG artifacts, than 4 non-balanced electrode system. Please note that 2 indifferent electrodes represent one electrode in relationship to a heart. At the same time 2 non-balanced EMG signals decrease the performance of a heart rate monitor during grasping, which is associated with exercise, **because it increases the level of EMG.**
Conclusion: ECG monitor with one indifferent electrode perform better than ECG monitor with two indifferent non-balanced electrodes.

Please look at the picture of the ECG Insta-Pulse in the book E-Factor. The 4 ECG electrodes were connected the following way:
One indifferent, One potential and Two electrodes connected together as One second potential. This system did not perform well and was discontinued. Please see electronic diagram on of this sensor on the Pic.28. But, if we would connected the same 4 non-balanced sensors as it shows on the Pic.2, the heart rate monitor would perform even worst than the ECG Insta-Pulse In the E-Factor book.

Pic.6

This picture shows another 4 electrodes, which are **non- balanced** sensors connected to an EMG monitor, called "Electronic Gym" The spaces between left and right electrodes are different, as could be seen. The geometry of electrodes is also different. Two middle electrodes are indifferent and two side electrodes are potential, as on the **Pic.1**
Sensors are not touched. The reading of the monitor is 0.

Please note, that the performance of this non-balanced sensor is similar to the performance of a **non- balanced** sensor on the Pic.1
For example the grasping of this sensor produced 1200 microvolt at the output of operational amplifier as it is shown on the Pic.7

Pic.7

This picture shows **Grasping** of 4 **non-balanced** sensors as per **Pic.6**.
EMG reading of this sensor at the output of differential amplifier monitored by EMG monitor is **1200 microvolt**.

It is clear from Pic.5 and Pic.7, that the performance of two different four non-balanced sensors produced an elevated EMG signal at the output of a differential amplifier and decreases the performance of an ECG heart rate monitor during grasping on exercise machines.

The elevated EMG at the output of differential amplifier is the result of an amplification by a differential amplifier of EMG left minus EMG right.

(Since EMG left could be much smaller or bigger than EMG right, the difference of the EMG signals could be of a substantial value, resulting in greater output of a differential amplifier.)

Pic. 8

This picture shows 4 electrodes, which are **balanced EMG** sensors connected to an EMG monitor, called "Electronic Gym" The spaces between left and right electrodes are the same, and sensor have a special geometry as it could be seen. Two middle electrodes are indifferent and two side electrodes are potential. Sensors are not touched. The reading of the monitor is 0.

Pic. 9

This picture shows the action of non-relaxed, but **Holding** normally of 4 balanced EMG sensors. EMG reading on the EMG monitor is 150 microvolt.

Pic.10

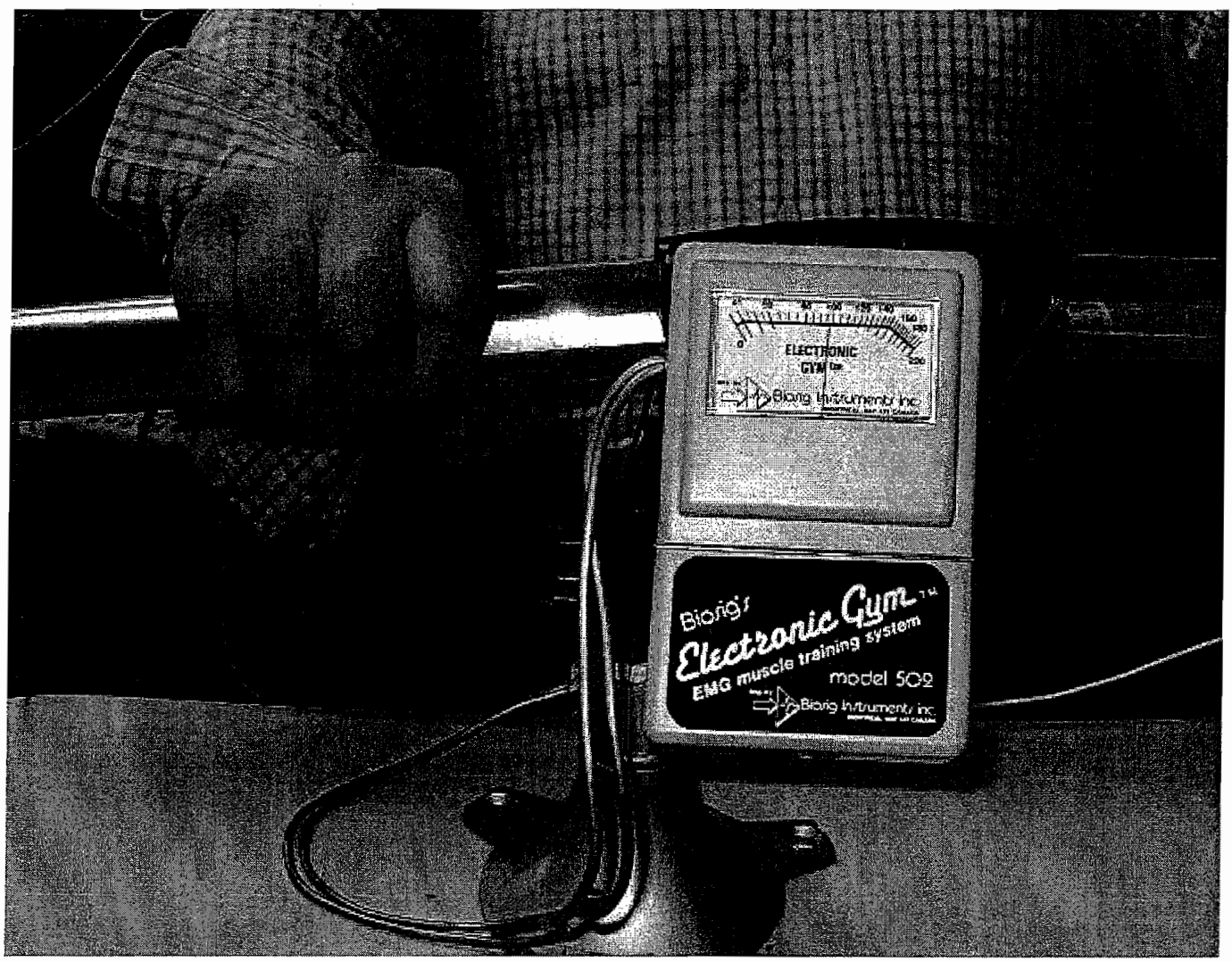
This picture shows **Grasping** and moving of 4 balanced EMG sensors. EMG reading of the monitor is **450 microvolt**.
This sensor was designed for a stepping machine where the hand movements are involved.
The sensor perfumed well on the commercial exercising product which was called Step Jet.

The prototype of the sensor described in the patent 4,444,200 has been produced and analyzed according to the description of the claim 1 and other descriptions of the patent.

Pic.11

The four electrode sensor has been connected according to the patent.
Two outer electrodes are potential and two inner electrodes are connecter together to a ground.
This sensor called ECG sensor, as per patent.
But we decided to test the level of EMG from these ECG electrodes at the output of a differential amplifier.

At Pic.11 **Sensors are not touched. The reading of the monitor is 0.**



Pic12

This picture shows the action of non-relaxed, but **Holding** normally of 4 non- balanced sensors. EMG reading on the EMG monitor is **950 microvolt.**

Please note that we are measuring the level of EMG signal at the output of differential amplifier, which is connected to two potential electrodes and two indifferent electrodes, which are connected to a ground.

The inventors did not know, that they elevated EMG signals on the palms of the hands since EMG is proportional to the surface of a contact, space between electrodes and geometry. This ECG electrodes have nothing to do with with 4 balanced EMG electrodes. That is why these is a non-balanced sensor and should be called as the 200 patent text called them, as ECG sensors.

Pic.13

This picture shows symmetrical **Grasping** of 4 **non-balanced sensors**.

EMG reading of this sensor at the output of differential amplifier, monitored by EMG monitor, is **1200 microvolt**.

It is clear that the performance of four non-balanced sensors produced an elevated EMG signal at the output of a differential amplifier and decreases the performance of an ECG heart rate monitor during grasping on exercise machines.

Conclusion: this sensor can't be balanced and used with a heart rate monitor on exercise machine.

Pic.14

This picture shows an asymmetrical Grasping, which is not advised by the inventors of 200 patent. The result is that EMG level at the output of differential amplifier is lower than symmetrical Grasp.

EMG reading of this sensor at the output of differential amplifier, monitored by EMG monitor, is **1000 microvolt**.

It shows again that these 4 electrodes can't be balanced.
That is why it should be called, as the 200 patent calls it, as an ECG sensor.

Pic.15

This picture shows the action of non-relaxed, but **Holding** normally 3 sensors, without touching the fourth sensor. EMG reading of the monitor is 450 microvolt . **This is much less than holding 4 non-balanced sensors.**

Conclusion the 3 ECG sensor works better than 4 non-balanced electrodes of ECG sensor of the patent 200.

This has been proved by almost 15 years the performance of the original 3 ECG Insta-Pulse heart rate monitors, design patented in Canada in 1977 and in the USA in 1980.

The old ECG Insta-Pulse performed very well during relaxing and holding of the unit. But it had limitation during **Grasping** and moving during exercise on the machines. **In these cases Biosig have used Tele-Pulse, a chest belt telemetry monitor, which were produced by Biosig and discontinued after Biosig started to sell a new patented EMG/ECG technology.**

Pic.16

Another symmetrical grasp of the sensor of 200 patent. The same as per Pic.13
EMG reading of the monitor is **1150 microvolt**

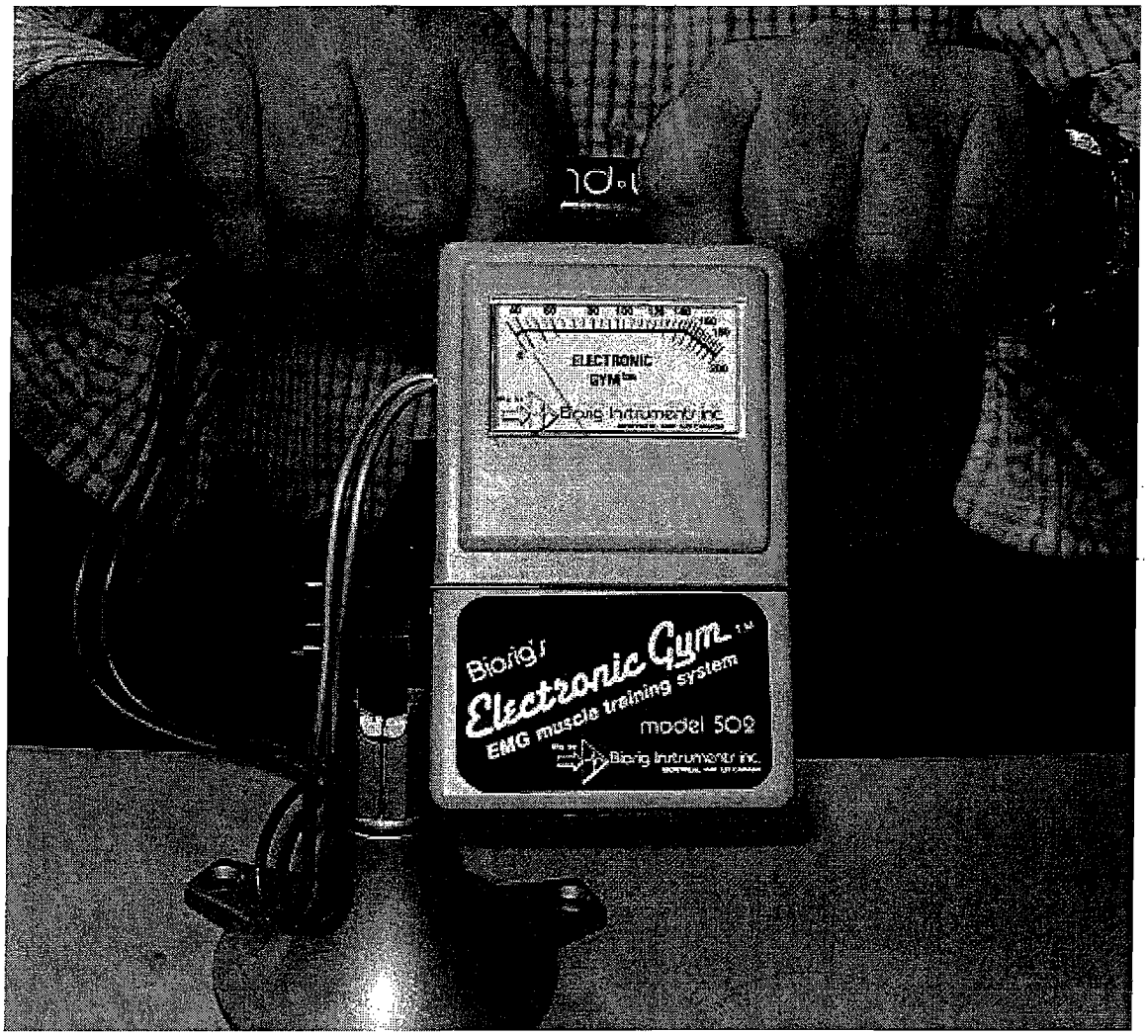
Conclusion:

The 200 patent sensor described in the claim 1, in pictures and in the text of the patent is a 3 sensor ECG monitor as per my original design patents of a 3 ECG heart rate monitor.
200 patent sensor can't be balanced, because the inventors did not know anything about surface EMG on the palms of the hands. The text of 200 patents never mentions about equal EMG on the palms of the hands.
The addition of the second ground electrode did not improve the performance of the three bi-polar ECG monitor.
The text of 200 patent mentioned" body noises", which have nothing to do with balanced EMG on the palms of the hands
The monitor described in 200 can not be used on exercise machines.
That is why it has been never been used on them.

Pic.17
3 ECG sensors grasp shows 700 microvolt VS symmetrical grasp on Pic.11 of 1200 microvolts.

Conclusion:

This sensor can not be balanced and should be used only as a 3 ECG bi-polar system only.



Pic.18

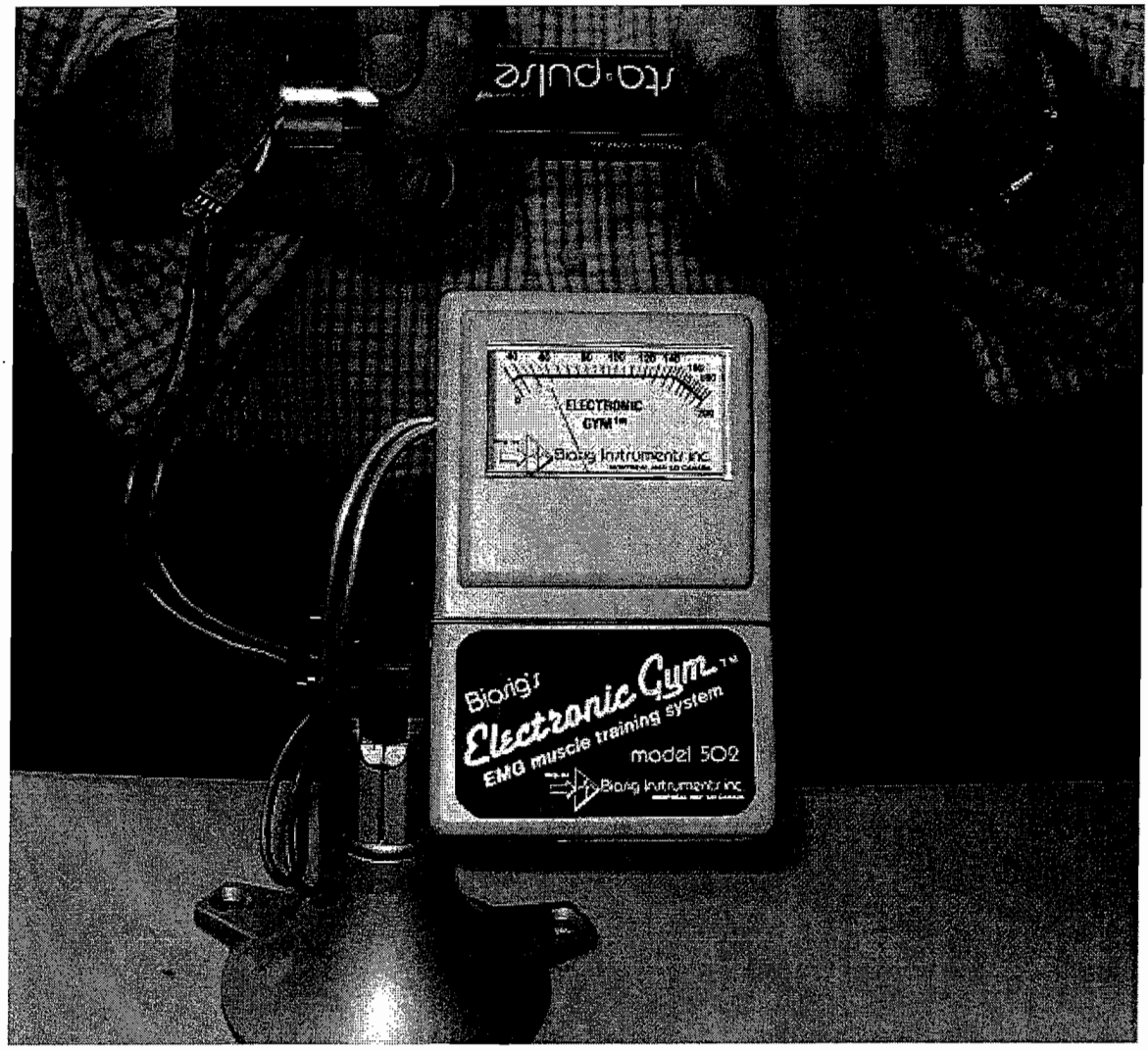
This picture shows the action of non-relaxed, but **Holding** normally of 4 balanced sensors an Insta-Pulse model 105.
EMG reading at the output of differential amplifier measured by the EMG monitor is 100 microvolt

Pic19

This picture shows the action of **Grasping** of 4 balanced EMG sensors of the Insta-Pulse model 105.. EMG reading on the EMG monitor is 300 microvolt.

Conclusion :

Insta-Pulse model 105 EMG sensors **are balanced sensors** do the fact that during design of the sensor the claim #1 of the patent, **5,337,753 was fully implemented. The EMG left and EMG right were balanced by size and space and geometry as it is a necessity in design of balanced EMG sensors.**



Pic.20

This picture shows **Grasping of** 3 sensors only, without touching the fourth sensor of the Insta-Pulse model 105
EMG reading at the output of differential amplifier is 550 microvolt .

Conclusion:

The 3 electrode Insta-Pulse perform much worst during exercise than 4 balanced EMG Insta-Pulse model 105.

Pic.21

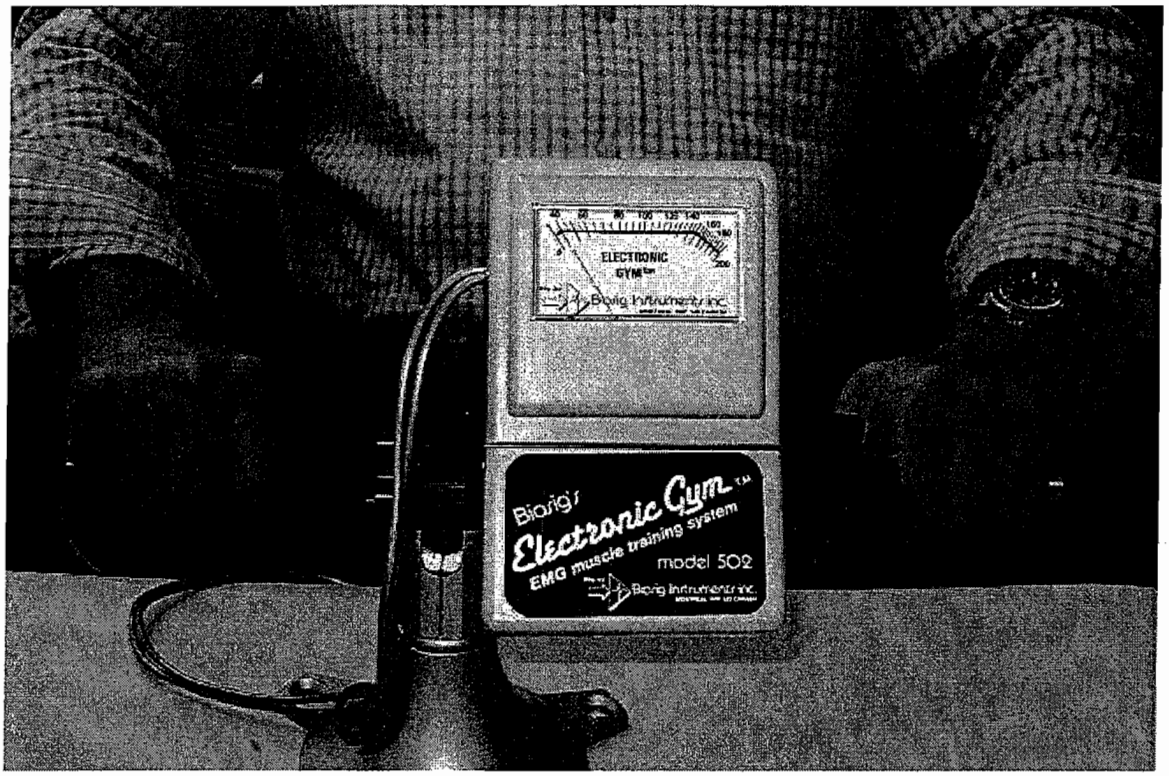
This picture shows the action of **Grasping** of **4 balanced** EMG sensors of the Nautilus EMG exercise bike. The reading on the EMG monitor is 380 microvolt.

Conclusion :

Nautilus bike EMG sensors are balanced EMG sensors do the fact, that during design of the sensor the claim 1 of the patent, **5,337,753 was fully implemented. The EMG left and EMG right were balanced by size, space and geometry as it is a necessity in design of the balanced EMG sensors.**

Please note that these sensors were not designed by Biosig.

The designers were following the teachings of the Biosig patent 5,337,753.



Pic22

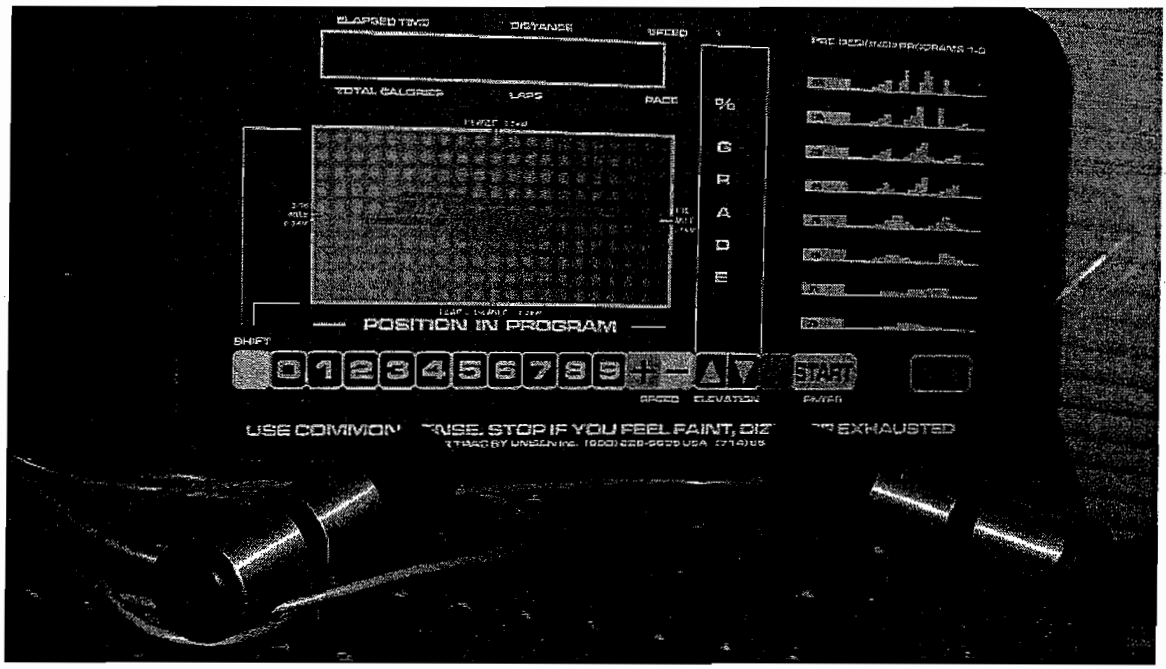
This picture shows the action of **Grasping** of 4 balanced EMG sensors of Star Trac by Unisen which were used on a treadmill. The reading on the EMG monitor is 370 microvolt.

Conclusion :

Star Trac EMG sensors are balanced EMG sensors do
the fact, that during design of the sensor the claim 1 of the patent, **5,337,753 was fully implemented. The EMG left and EMG right were balanced by size, space and geometry, as it is a necessity in design of the balanced EMG sensors.**

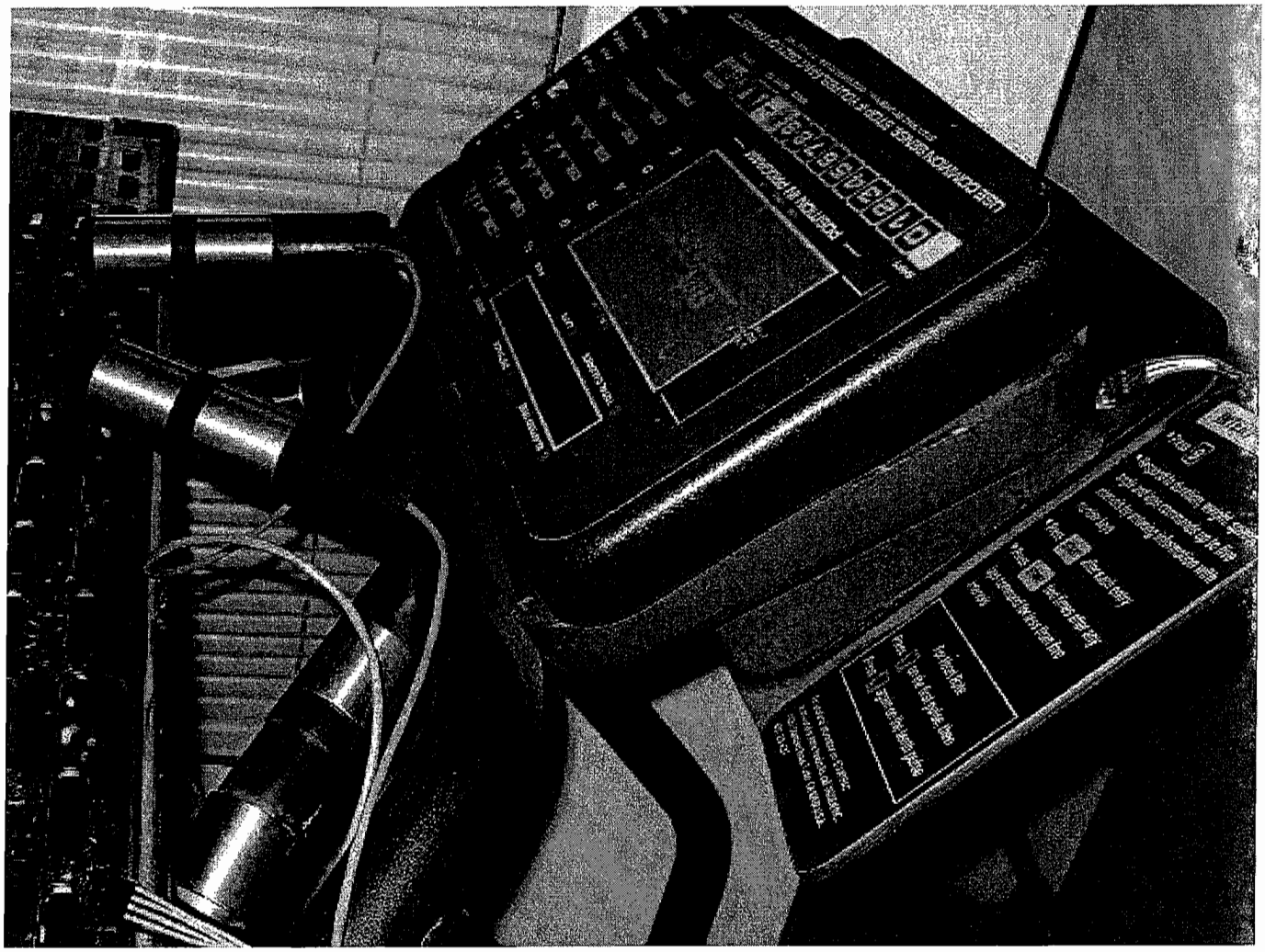
Please note that these sensors were not designed by Biosig. Biosg only consulted the Star Trac personal to follow the teachings of Biosig patent. Star Trac send the treadmill with unbalanced EMG sensors to

Biosig. Biosig advised Star Trac to balance the sensors by changing the space between EMG electrodes in order to obtain equal EMG from left and right palms of the hands during Grasping of the sensors.
The designers started to follow the teachings of the Biosig patent 5,337,753. and achieved a great performance of their exercise equipment. Biosig supplied Star Trac with the PCB only, but Star Trac were producing balanced EMG sensors.
Please refer to the Pic22 and Pic.23

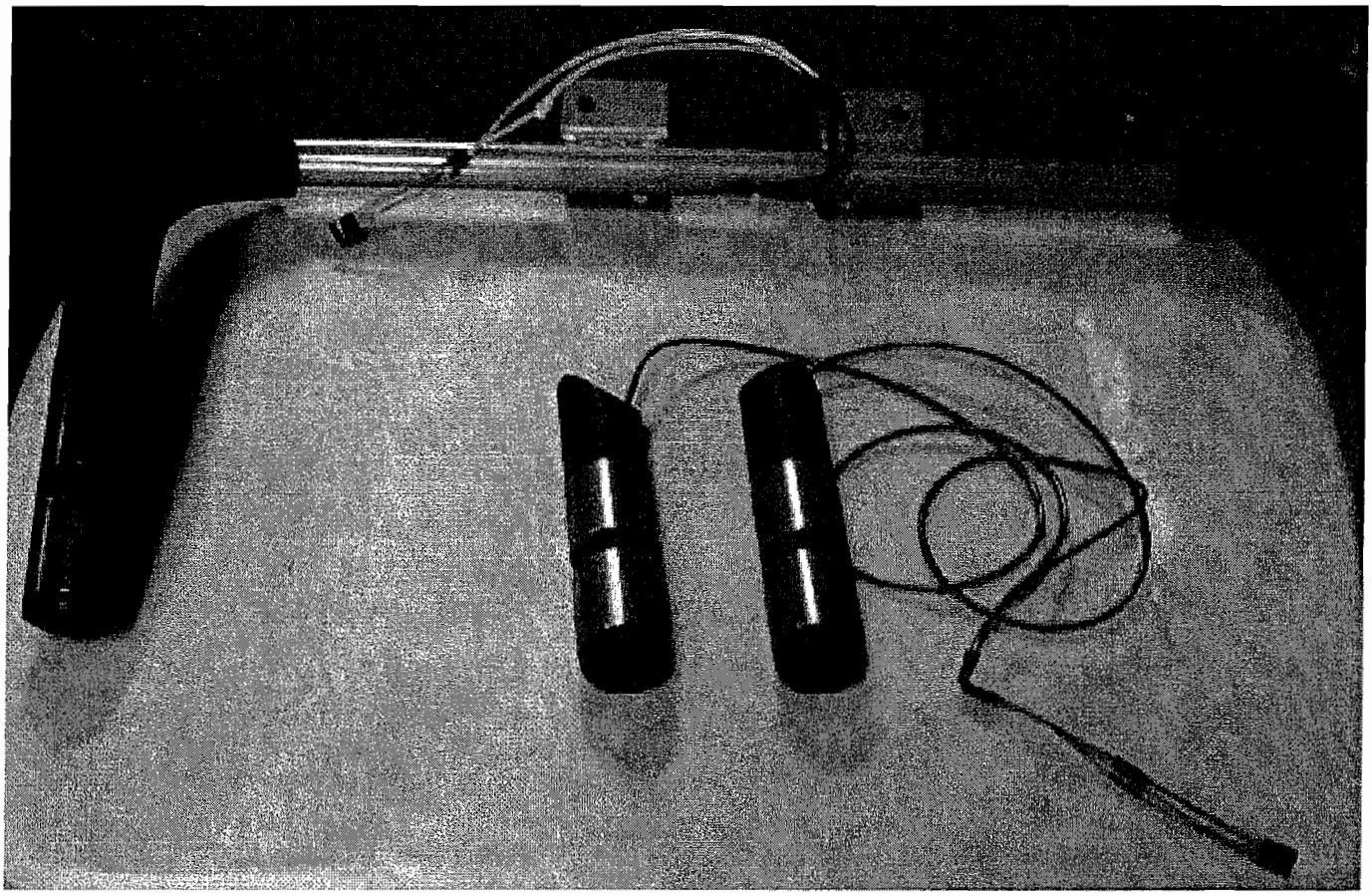


Pic.23

Balanced EMG Star Trac sensors connected to Star Trac fitness computer. Biosig supplied the PCB as per claim#1 of Biosig Patent **5,337,753.**

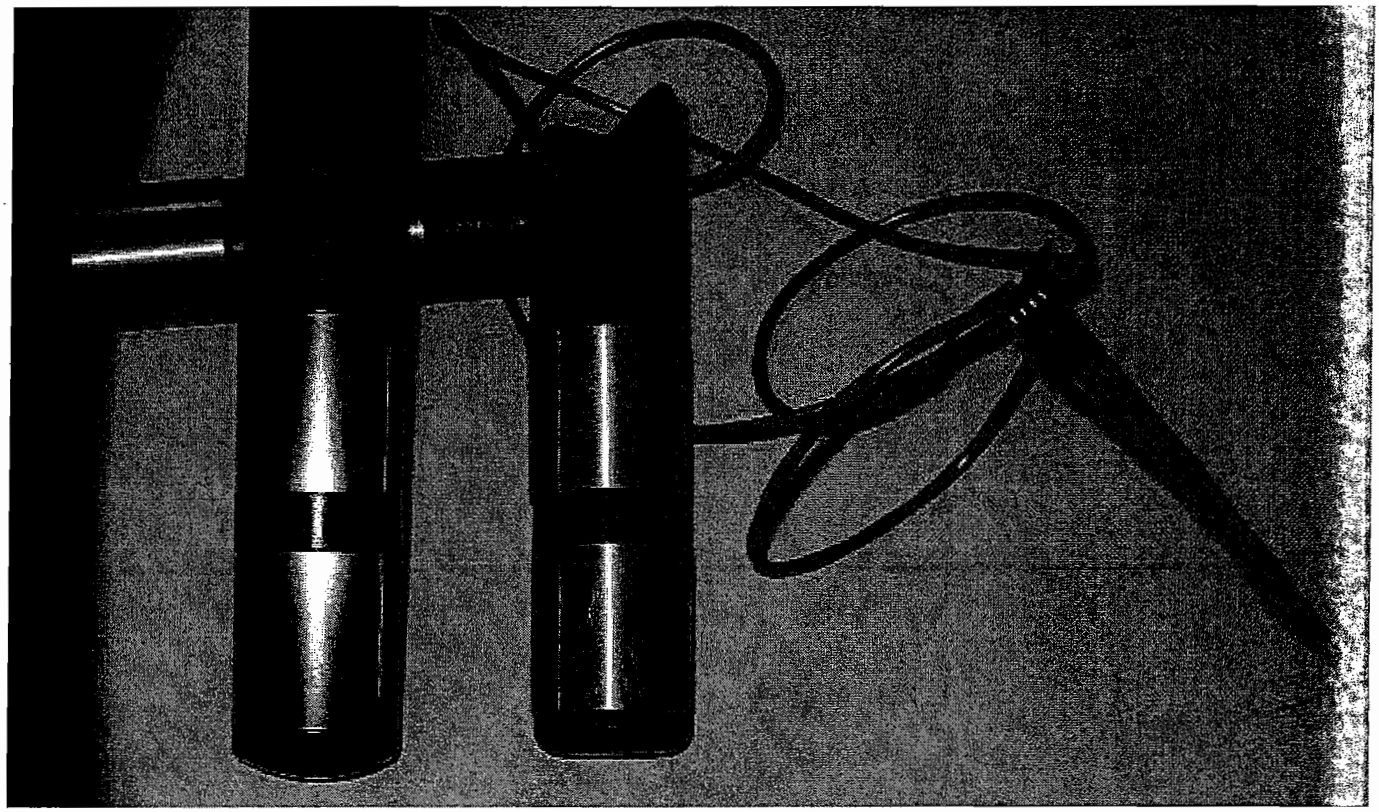


Pic.24
This picture shows a pair of balanced EMG electrodes and a pair of non-balanced electrodes on Strar Trac treadmill, which has been sent to Biosig and is located at Biosig R&D office.



Pic25

This picture shows the balanced EMG sensors developed by Star Trac. These sensors are in the middle.
Also shown balanced EMG sensors developed by Schwinn brand of Nautilus.

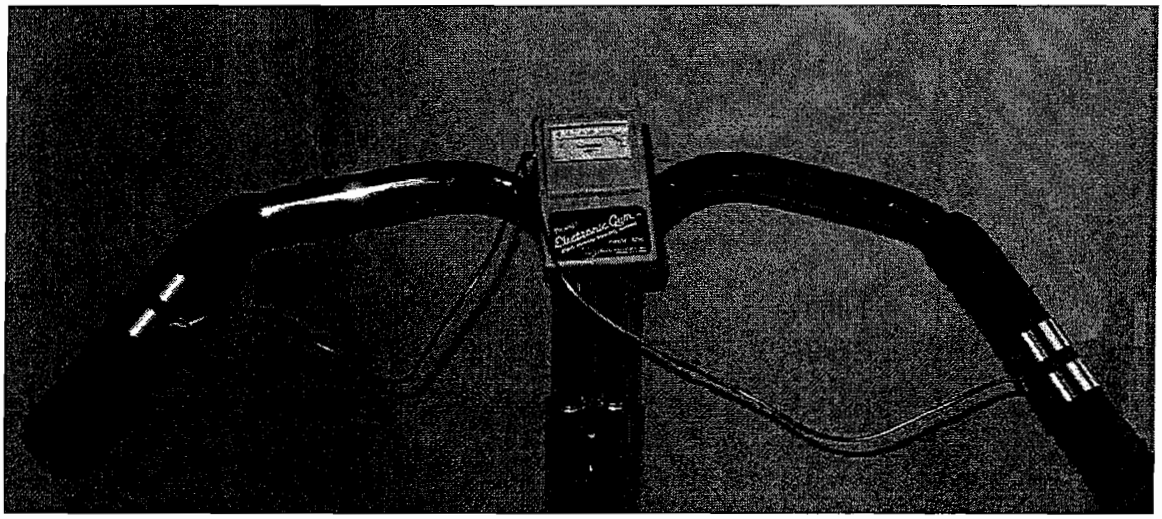


Pic.26

This picture shows the geometry of Star Trac EMG sensors (sensor on the right) and Schwinn brand by Nautilus EMG sensors (sensor on the left)

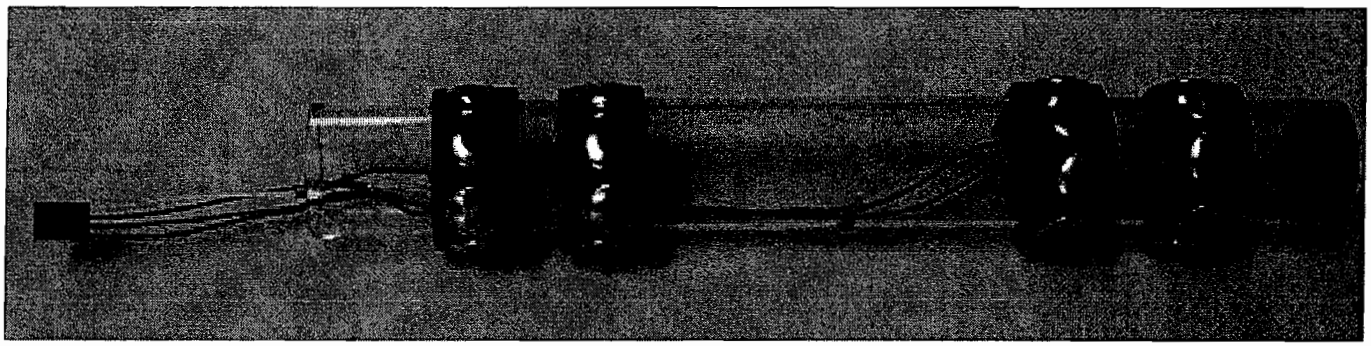
The both sensors were tested by Biosig using the measurement of the output of a differential amplifier by EMG monitor.

Both sensors are balanced EMG sensors as per claim# 1 of Biosig patent **5,337,753.**



Pic.27

This picture shows Biosig system for design and balancing of EMG sensors for exercise machines.
It consist of moving handle bars and EMG monitor which measures the output of differential amplifier.
EMG monitor measure EMG signal at the output of a differential amplifier at the same frequency band as "R" wave of an ECG signal.

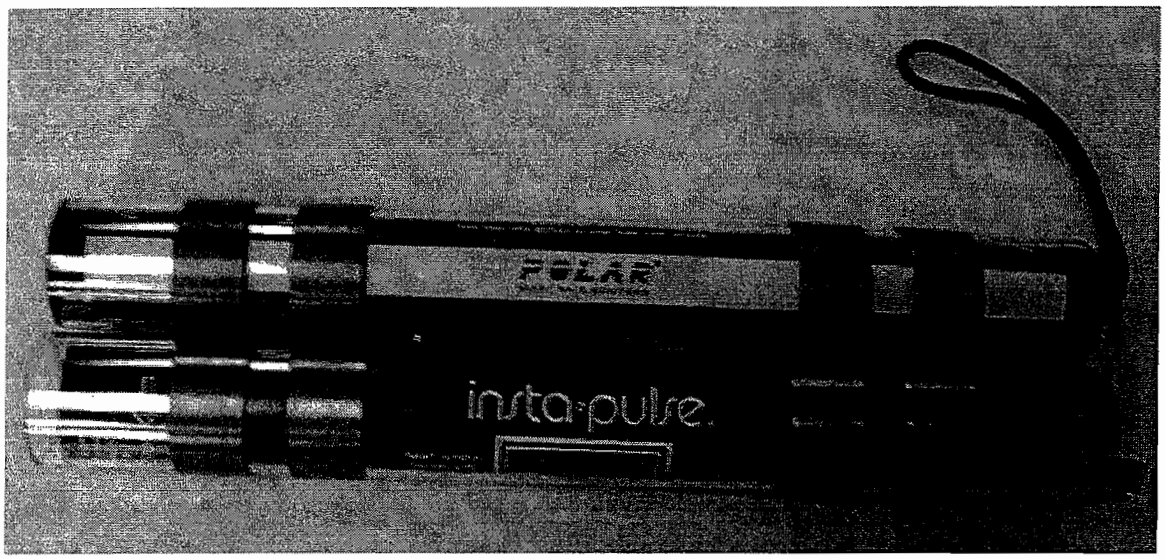


Pic.28

This picture shows the first prototype during the search of how to balance the EMG on the left and right palms of the hands.
We have used individual small round EMG sensors connected in order to balance the EMG signals.
As the result of this work we have confirmed the laws of the surface EMG.

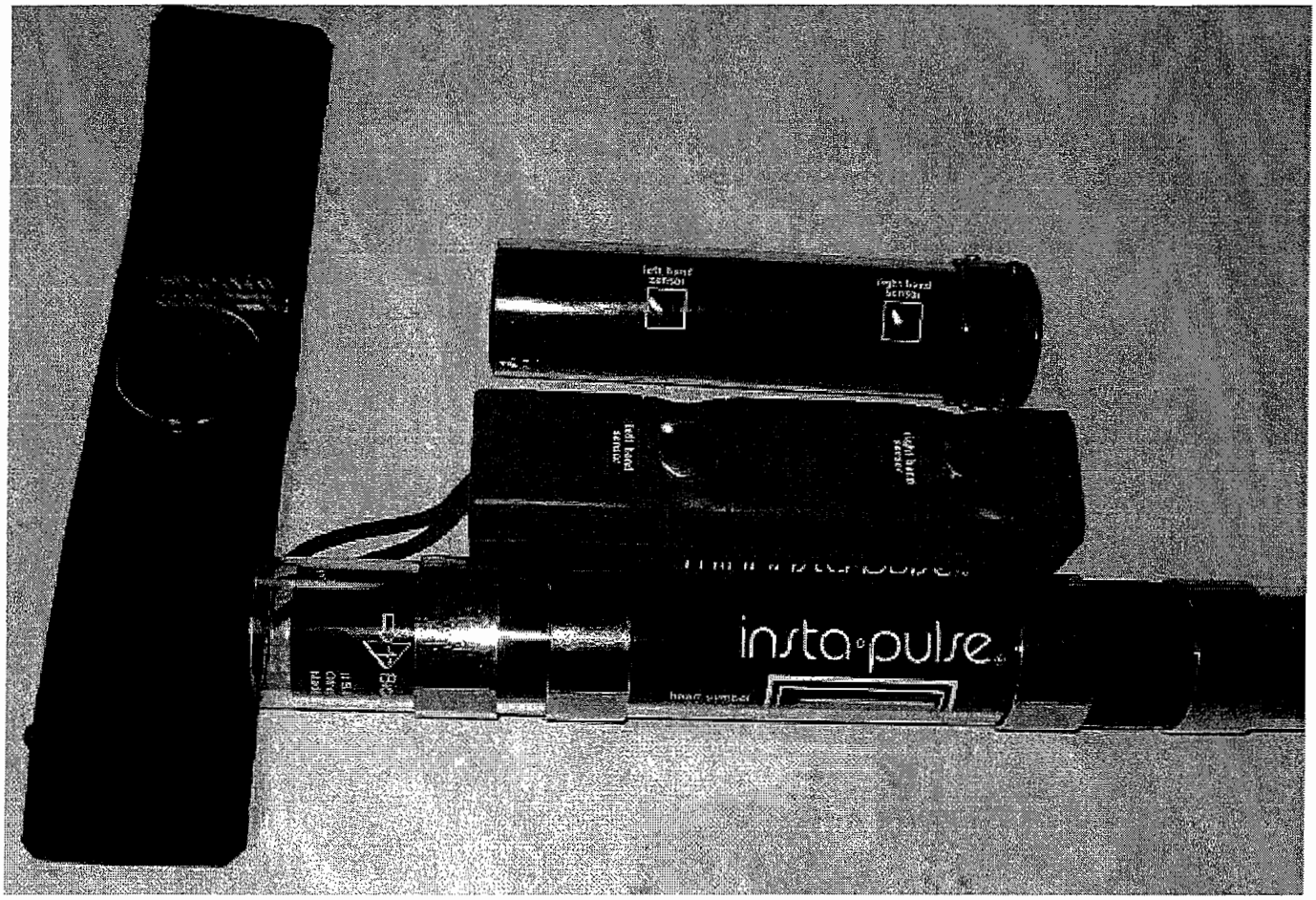
Pic.29

This picture shows the sensors, which were used in the test on 04/30/2009



Pic.30

This picture shows Insta-Pulse EMG balanced sensor produced by Biosig.
This picture also shows the same sensor, which was **produced by Biosig for Polar**



Pic31

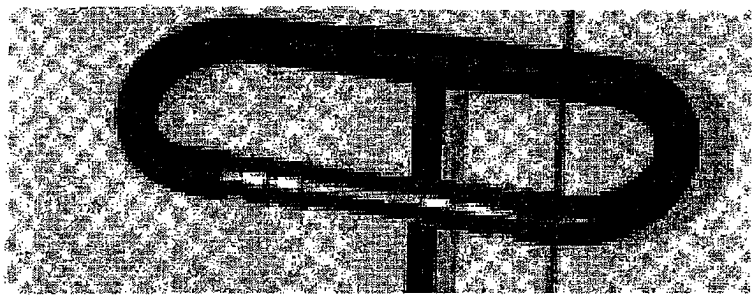
This picture shows ECG sensors which were shown in the book E-Factor.

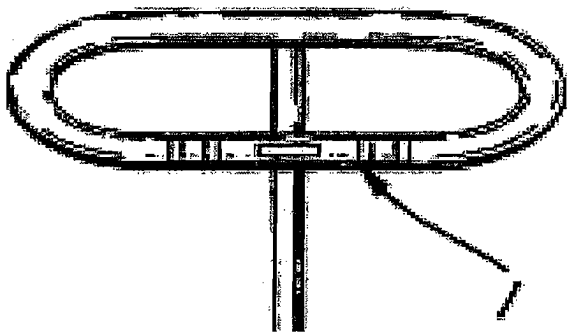
As it is clear from the picture and **the tests above**, these sensors are not balanced ECG sensors. All this sensors and heart rate monitors associated with these sensors and Tele-Pulse chest belt radio telemetry heart rate monitor were **discontinued from Biosig production after the invention of the Biosig EMG/ECG technology patent 5,337,753.**

Insta-Pulse with 4 non-balanced electrodes, which are ECG electrodes were shown, tested and described on the Pic.1 and Pic.5

Please note, that all these sensors on PIc.31 represent ECG bi-polar technology, which was design patented by Biosig in 1977 and in 1980.

Please also note that the text of the chapter XIX on "High-Tech Pulse Monitoring" in "E-Factor" has never mentioned anything about EMG/ECG technology or equal EMG from the right and left palms of the hands or close to "0" output of differential amplifier as the indicator of the balancing of EMG.



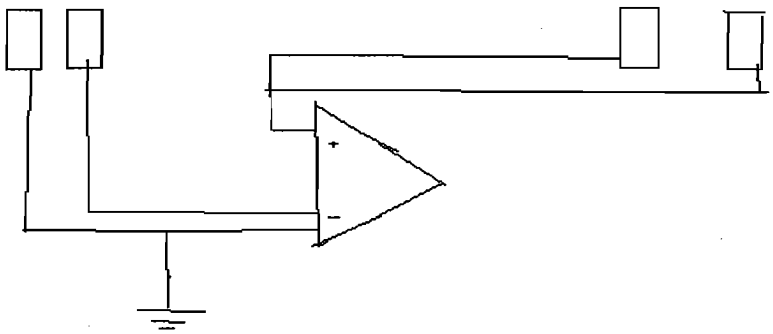


Pic.32

This picture shows two separate items presented by Nautilus to the PTO of the USA.

1.The picture above is the picture from the book E-Factor. This picture Clearly shows that ECG electrodes, which were described above in Pic.1 and Pic.5 This picture #32 clearly shows non-balanced electrodes. The space between left pair of electrodes is much smaller than the space between right pair of electrodes.

2. The picture below shows balanced EMG electrodes as per Biosig patent 5,337,753. Nautilus describes these two different pictures of sensors as the same picture. That is a huge misrepresentation of the real facts.



Pic.33
This picture show the electronic diagram of the connections of the 4 ECG sensors presented in the book E-Factor, as shown on the Pic.32
If these non- balanced ECG sensors of Pic.32 would be connected as per Pic.5, the sensor would perform much worst than 3 ECG sensor system, which is shown in E-Factor and in Pic.32

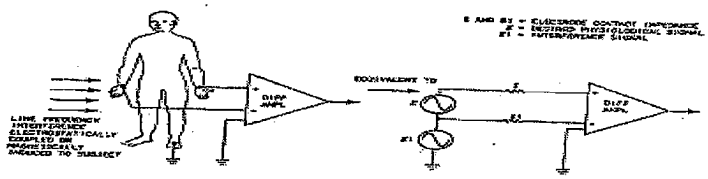


Fig. 19-1. Typical physiological measurement configuration.

Pic.34
This picture, presented by Nautilus to US PTO, clearly demonstrates Bi-polar ECG. The location of the indifferent electrode in not important for a non-diagnostic fitness Bi-polar ECG monitoring in association with a heart rate monitor, because we need only “R” wave of the ECG to calculate a heart rate. The number on indifferent electrodes is not important for “R” wave ECG monitoring, because the generator of ECG is a heart and not the palms of the hands.
Palms of the hands generate EMG and not an ECG signal.
Palms of the hands are only the conductors of the ECG signal, which is generated by a heart and present as impedance to the ECG signal.
This is confirmed by the text of the **Pic34**

EXHIBIT 12

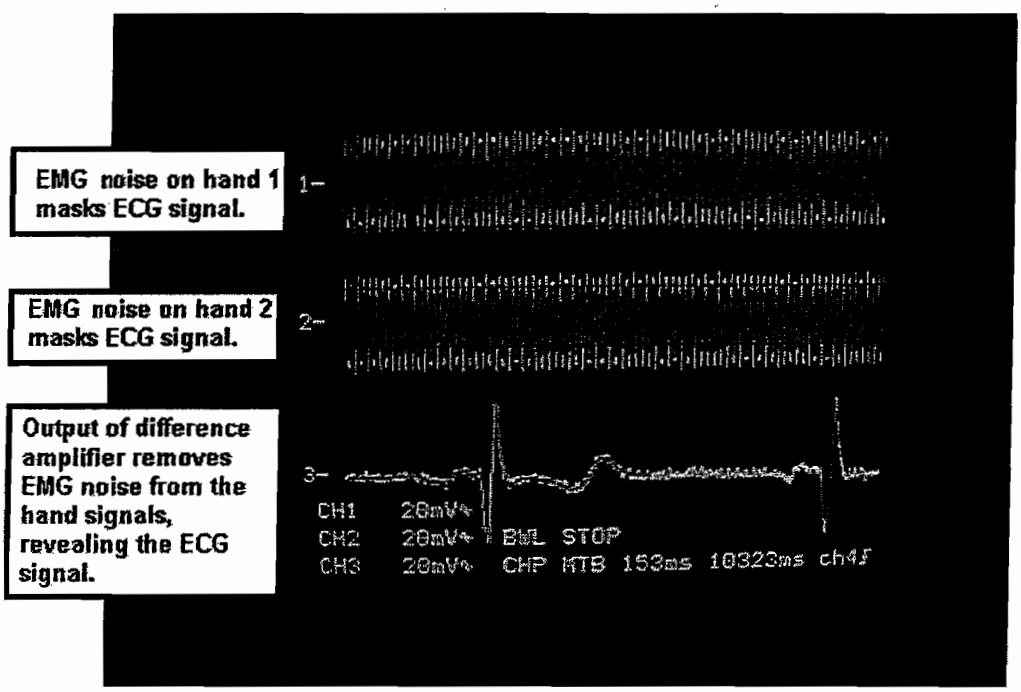

EMG noise on hand 1 masks ECG signal.
EMG noise on hand 2 masks ECG signal.
Output of difference amplifier removes EMG noise from the hand signals, revealing the ECG signal.
1-
2-
3-
CH1 20mV
CH2 20mV
CH3 20mV
B&L STOP
CHP HTB 153ms 10323ms ch4

EXHIBIT 13

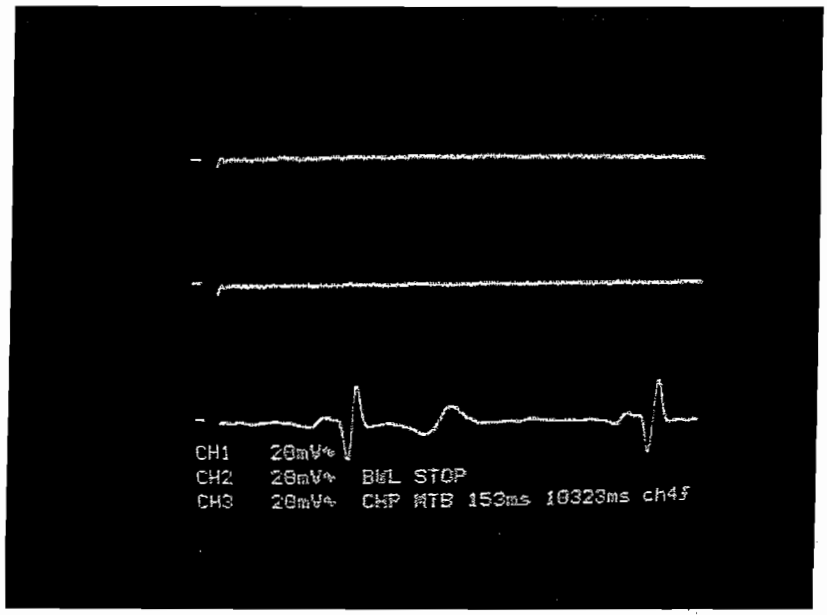

CH1 20mV/
CH2 20mV/ B&L STOP
CH3 20mV/ CHP MTB 153ms 10323ms ch4f

EXHIBIT 14

The amplitude of EMG and ECG in Microvolts	Relaxed holding baton monitor	Non-relaxed holding baton monitor	Grasping baton monitor
ECG amplitude at the output of differential amp. '200 device	1050	1050	1050
ECG amplitude at the output of differential amp. '753 device	1000	1000	1000.
EMG amplitude at the output of differential amp '200 device	100	950	1200
EMG amplitude at the output of differential amp '753 device	20	100	300
ECG/EMG ratio '200 device	10.5	1.105	0.875
ECG/EMG ratio '753 device	50	10	3.3

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/010,366	12/19/2008	5337753	8185-82247-01	8551

2543 7590 04/13/2009

ALIX YALE & RISTAS LLP
750 MAIN STREET
SUITE 1400
HARTFORD, CT 06103

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 04/13/2009

Please find below and/or attached an Office communication concerning this application or proceeding.

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EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/010,366*.

PATENT NO. *5337753*.

ART UNIT *3992*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

PTOL-465 (Rev.07-04)

Office Action in Ex Parte Reexamination	Control No. 90/010,366	Patent Under Reexamination 5337753	
	Examiner ALEXANDER J. KOSOWSKI	Art Unit 3992	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

a☒ Responsive to the communication(s) filed on *12/19/08* . b☐ This action is made FINAL.
c☒ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire *2* month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Information Disclosure Statement, PTO/SB/08.
3. ☐ Interview Summary, PTO-474.
4. ☐ ___.

Part II SUMMARY OF ACTION

1a. ☒ Claims *1-16* are subject to reexamination.
1b. ☐ Claims ___ are not subject to reexamination.
2. ☐ Claims ___ hav e been canceled in the present reexamination proceeding.
3. ☒ Claims 9 are patentable and/or confirmed.
4. ☒ Claims ~~1-16~~ 1-8, 10-16 are rejected.
5. ☐ Claims ___ are objected to.
6. ☐ The drawings, filed on ___ are acceptable.
7. ☐ The proposed drawing correction, filed on ___ has been (7a) ☐ approved (7b)☐ disapproved.
8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   1☐ been received.
   2☐ not been received.
   3☐ been filed in Application No. ___.
   4☐ been filed in reexamination Control No. ___.
   5☐ been received by the International Bureau in PCT application No. ___.
   * See the attached detailed Office action for a list of the certified copies not received.
9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.
10. ☐ Other: _____

cc: Requester (if third party requester)

DETAILED ACTION

1) This Office action addresses claims 1-16 of United States Patent Number 5,337,753 (Lekhtman), for which it has been determined in the Order Granting Ex Parte Reexamination (hereafter the "Order") mailed 2/5/09 that a substantial new question of patentability was raised in the Request for *Ex Parte* reexamination filed on 12/19/08 (hereafter the "Request").

References Utilized

U.S. Pat 4,444,200 (Fujisaki)

Trademark Specimen, Reg. No. 1,156,243 (Biosig)

The "E" Factor Book (E-Factor)

Claim Rejections - 35 USC § 102

2) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3) Claims 1-3 are rejected under 35 U.S.C. 102(b) as being unpatentable by Fujisaki et al (U.S. Pat 4,444,200).

Referring to claim 1, Fujisaki teaches a heart rate monitor for use by a user in association with exercise apparatus and/or exercise procedures, comprising;

an elongate member (Figure 1);

electronic circuitry including a difference amplifier having a first input terminal of a first polarity and a second input terminal of a second polarity opposite to said first polarity (col. 3 lines 3-10 and Figure 3, whereby a differential amplifier is utilized);

said elongate member comprising a first half and a second half (Figure 1);

a first live electrode and a first common electrode mounted on said first half in spaced relationship with each other and a second live electrode and a second common electrode mounted on said second half in spaced relationship with each other (col. 2 lines 43-63 and col. 3 lines 3-10 and Figures 2-3, whereby left and right hand grips and inner and outer electrodes are used);

said first and second common electrodes being connected to each other and to a point of common potential (col. 3 lines 10-13 and Figure 1, whereby ground is considered the point of common potential);

said first live electrode being connected to said first terminal of said difference amplifier and said second live electrode being connected to said second terminal of said difference amplifier (col. 3 lines 3-10 and Figures 1 and 3, whereby love electrode connections are attached to inputs of the differential amplifier);

a display device disposed on said elongate member (Figure 1, #12);

wherein, said elongate member is held by said user with one hand of the user on said first half contacting said first live electrode and said first common electrode, and with the other hand of the user on said second half contacting said second live electrode and said second common electrode (col. 4 lines 46-48, whereby grip sensors are used with two contacts each);

whereby a first electromyogram signal will be detected between said first live electrode and said first common electrode, and a second electromyogram signal, of substantially equal magnitude and phase to said first electromyogram signal will be detected between said second live electrode and said second common electrode so that, when said first electromyogram signal

is applied to said first terminal and said second electromyogram signal is applied to said second terminal, the first and second electromyogram signals will be subtracted from each other to produce a substantially zero electromyogram signal at the output of said difference amplifier, and whereby a first electrocardiograph signal will be detected between said first live electrode and said first common electrode and a second electrocardiograph signal, of substantially equal magnitude but of opposite phase to said first electrocardiograph signal will be detected between said second live electrode and said second common electrode; so that, when said first electrocardiograph signal is applied to said first terminal and said second electrocardiograph signal is applied to said second terminal, the first and second electrocardiograph signals will be added to each other to produce a non-zero electrocardiograph signal at the output of said difference amplifier (Fujisaki, col. 3 lines 13-26, col. 4 lines 40-61 and Figure 3, whereby the circuit configuration taught by Fujisaki fully anticipates the claimed limitations, and whereby utilizing a differential amplifier circuit as taught by Fujisaki results in the desired output which would add or subtract both input signals depending on input, and whereby Fujisaki teaches two live and two common electrodes to be gripped by opposite hands for measuring pulse rate signals);

means for measuring time intervals between heart pulses on detected electrocardiograph signal (col. 3 lines 3-26 and Figure 3, whereby a filter and pulse generator are utilized to create output pulses on every heart beat to measure time intervals);

means for calculating the heart rate of said user using said measure time intervals (col. 3 lines 28-38, whereby a microprocessor calculates heart rate);

said means for calculating being connected to said display device, whereby, the heart rate of said user is displayed on said display device (Figure 3 and col. 4 lines 52-59, whereby a display is coupled to the microprocessor).

Referring to claim 2, Fujisaki teaches wherein said elongate member comprises a hollow cylindrical member, said electronic circuitry being housed in the interior of said hollow cylindrical member (Figure 1, whereby a center casing with cylindrical members houses the electronic circuitry).

Referring to claim 3, Fujisaki teaches wherein said first live electrode comprises a first ring member of a conductive material mounted on said first half of said elongate member, and wherein said first common electrode comprises a second ring member of a conductive material mounted on said first half of said elongate member and spaced from said first ring member, and wherein said second live electrode comprises a third ring member of a conductive material mounted on said second half of said elongate member and wherein said second common electrode comprises a fourth ring member of a conductive material mounted on said second half of said elongate member and spaced from said third ring member (Figures 1 and 2, whereby there are four ring members that form the electrodes, and spacers separate the live electrodes).

Claim Rejections - 35 USC § 103

4) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5) Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable by Fujisaki et al (U.S. Pat 4,444,200).

Referring to claim 4, Fujisaki teaches wherein said means for measuring time intervals comprises a bandpass filter, the output of said difference amplifier being connected to an input of said bandpass filter; and wherein said means for calculating the heart rate comprises; a microprocessor, the output of circuit elements being connected to an input of said microprocessor; the output of said microprocessor being connected to said display device (Figure 3 and col. 3 lines 3-26 and col. 4 lines 52-59, whereby a filter is connected to outputs of the differential amplifier and input into the microprocessor, and whereby time intervals of pulses are measured and utilized to computer and display the heart rate). However, Fujisaki teaches that the output of the filter is sent to a pulse generator, and not specifically a threshold limiter.

Examiner notes that the threshold limiter as claimed is defined in the specification as being utilized to produce square pulses to be send to the microprocessor. The pulse generator taught by Fujisaki is also utilized to generate rectangular pulse signals. Therefore, both elements are functionally equivalent.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to utilize a pulse generator as taught by Fujisaki as a type of threshold limiter in the invention taught above since these would both produce square waves from the output of a bandpass filter, and since threshold limiters are well known in the art.

6) Claims 5-8, 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujisaki, further in view of Biosig, further in view of E-Factor.

Referring to claims 5-8, 10-12, Fujisaki teaches the above, However, Fujisaki does not explicitly teach that said display device comprises a pulse indicator adapted to be illuminated each time a heart pulse of the user is detected, that elasticized plugs force-fit into both ends of said cylindrical member, whereby, the interior of said hollow cylindrical member is waterproofingly sealed, including a stand means for mounting the monitor on the floor; said stand means including a base and an upwardly extending member, including a means for mounting said monitor on a wall; said means comprising a base, wherein said cylindrical member is mounted on an exercise apparatus, wherein said elongate member is mounted on an exercise apparatus, and wherein said electronic circuitry being mounted in said exercise apparatus, wherein said elongate member comprises a hollow cylindrical member.

Biosig teaches a 3 digit numerical indication of pulse rate along with a red dot that illuminates during a user's pulse (Exhibit 5), E-Factor teaches a watertight enclosure (Page 245), Biosig teaches plugs in the end of an elongate member (Exhibit 5, whereby examiner takes official notice that elasticized materials are well known in the art), E-Factor teaches a stand means and wall bracket with base (Pages 244-245), E-Factor teaches the use of pulse meters while exercising and teaches that pulse meters can be mounted and integrated into exercise bikes (Pages 244-247), and Biosig teaches that the elongate member comprises a hollow cylindrical member.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to utilize the limitations above in the invention taught by Fujisaki since heart-rate monitors are well known as a guide in exercise, and provide personal motivation, preventative diagnostic tools, and biofeedback instruments all in one (E-Factor, page 244), since E-Factor discusses Biosig products specifically, and since examiner notes indication of pulse would provide multiple types of visual feedback for users during exercise.

Referring to claim 13, Fujisaki teaches that said first live electrode comprises a first ring member of a conductive material mounted on said first half of said elongate member, and wherein said first common electrode comprises a second ring member of a conductive material mounted on said first half of said elongate member and spaced from said first ring member; and wherein said second live electrode comprises a third ring member of a conductive material mounted on said second half of said elongate member and wherein said second common electrode comprises a fourth ring member of a conductive material mounted on said second half of said elongate member and spaced from said third ring member (Figures 1-2 and col. 2 lines 43-48, whereby four rings are cylindrical conductive electrodes with spacers).

Referring to claim 14, see rejection of claim 4 above.

Referring to claim 15, see rejection of claim 5 above.

Referring to claim 16, see rejection of claim 6 above.

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

7) Claim 9 is confirmed.

The following is an examiner's statement of reasons for patentability and/or confirmation of the claim found patentable in this reexamination proceeding:

The prior art of record, alone or in combination, does not explicitly teach a heart rate monitor including insert means, said insert means comprising a paper-like material having graphics and alphabetic information imprinted on one surface thereof; said hollow cylindrical member comprising a transparent material; said insert means being inserted into said hollow cylindrical member such that the graphics are disposed against the wall of said hollow cylindrical member so that said graphics can be seen on the outside of said hollow cylindrical member, in combination with the remaining elements or features of the claimed invention.

Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation" and will be placed in the reexamination file.

Conclusion

All correspondence relating to this ex parte reexamination proceeding should be directed as follows:

By U.S. Postal Service Mail to:

Mail Stop Ex Parte Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX to:

(571) 273-9900
Central Reexamination Unit

By hand to:

Customer Service Window
Randolph Building
401 Dulany St.
Alexandria, VA 22314

By EFS-Web:

Registered users of EFS-Web may alternatively submit such correspondence via the electronic filing system EFS-Web, at

https://sportal.uspto.gov/authenticate/authenticateuserlocalepf.html

EFS-Web offers the benefit of quick submission to the particular area of the Office that needs to act on the correspondence. Also, EFS-Web submissions are "soft scanned" (i.e., electronically uploaded) directly into the official file for the reexamination proceeding, which offers parties the opportunity to review the content of their submissions after the "soft scanning" process is complete.

14) Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

/Alexander J Kosowski/

Primary Examiner, Art Unit 3992

ESK

Reexamination	Application/Control No.	Applicant(s)/Patent Under Reexamination
	90/010,366	5337753
	Certificate Date	Certificate Number

Requester **Correspondence Address:** ☐ **Patent Owner** ☒ **Third Party**

Robert F. Scotti
Klarquist Sparkman, LLP
121 SW Salmon Street, Suite 1600
Portland, OR 97204

LITIGATION REVIEW ☒	**AJK** (examiner initials)	**4/7/09** (date)
Case Name		Director Initials
OPEN: 1:04cv6654 Biosig Instruments v. The Nautilus Group		Eric Frend to GM
CLOSED: 1:05cv893, 1:05cv855, 1:04cv6927, 1:04cv11846		↓
CLOSED: 1:01cv108, 1:01cv57		

COPENDING OFFICE PROCEEDINGS	
TYPE OF PROCEEDING	**NUMBER**
1. no copending office proceedings	
2.	
3.	
4.	

66155 U.S. PTO

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
***EX PARTE* REEXAMINATION**

U.S. Patent No.: 5,337,753

Grant Date: August 16, 1994

Owner: Biosig Instruments Inc.

Title: Heart Rate Monitor

Reexam Control No. 90/010,366
TC/A.U.: 3992
Examiner: Alexander Kosowski

Docket No.: LEK/151/US

Mail Stop Ex Parte Reexam
Attn: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEARANCE AND CHANGE OF ADDRESS

The undersigned represents Biosig Instruments Inc., the owner of the subject patent under reexamination, and hereby requests that further communications be sent to:

Customer No. 002543

Alix, Yale & Ristas, LLP
750 Mail Street
Suite 1400
Hartford, Connecticut 06103-2721

No patent Owner's Statement pursuant to 37 C.F.R. §1.530 will be filed.

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited on the date below with the United States Postal Service as first class mail in an envelope addressed to "Mail Stop Ex Parte Reexam, Attn: Central Reexamination Unit, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450."

Signature: _____ Reg. No. 28,663 Date: April 3, 2009
L. James Ristas

U.S. Patent No.: 5,337,753
Grant Date: August 16, 1994

The undersigned certifies that a copy of this paper was served on the requestor, Nautilus, Inc., pursuant to 37 C.F.R. §1.248(a)(4) on April 3, 2009, by mailing to Robert F. Scotti, Klarquist Sparkman, LLP, 121 SW Salmon Street, Suite 1600, Portland, Oregon 97204.

Respectfully submitted,

BIOSIG INSTRUMENTS INC.

By _____
L. James Ristas
Registration No. 28,663
Alix, Yale & Ristas, LLP
Attorney for Applicant

Date: April 3, 2009
750 Main Street, Suite 1400
Hartford, CT 06103-2721
Telephone No. (860) 527-9211
Our Ref: LEK/151/US

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/010,366	12/19/2008	5337753	8185-82247-01	8551

7590 02/05/2009

CHILTON, ALIX & VAN KIRK
750 Main Street
Hartford, CT 06103-2708

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 02/05/2009

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

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(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

Robert F. Scotti

Klarquist Sparkman, LLP

121 SW Salmon Street, Suite 1600

Portland, OR 97204

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/010,366*.

PATENT NO. *5337753*.

ART UNIT *3992*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Granting / Denying Request For Ex Parte Reexamination	Control No.	Patent Under Reexamination	
	90/010,366	5337753	
	Examiner	Art Unit	
	ALEXANDER J. KOSOWSKI	3992	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The request for *ex parte* reexamination filed *19 December 2008* has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a)☐ PTO-892, b)☒ PTO/SB/08, c)☒ Other: *Decision*

1. ☒ The request for *ex parte* reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's Reply (optional): TWO MONTHS from the **date of service** of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

2. ☐ The request for *ex parte* reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181 within ONE MONTH from the mailing date of this communication (37 CFR 1.515(c)). **EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

a) ☐ by Treasury check or,

b) ☐ by credit to Deposit Account No. _____, or

c) ☐ by credit to a credit card account, unless otherwise notified (35 U.S.C. 303(c)).

cc:Requester (if third party requester)

DECISION

1) A substantial new question of patentability affecting claims 1-16 of United States Patent Number 5,337,753 (Lekhtman) is raised by the request for *ex parte* reexamination filed 12/19/08.

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

References Cited in the Request

U.S. Pat 4,444,200 (Fujisaki)

Trademark Specimen, Reg. No. 1,156,243 (Biosig)

The "E" Factor Book

U.S. Pat 4,248,244 (Charnitski)

The Biophysical Measurements Book

Identification of Every Claim for Which Reexamination is Requested

2) The five references cited above are discussed regarding claims 1-16 of the Lekhtman patent. Requestor has proposed 6 possible combinations of rejections, all utilizing the Fujisaki reference as a base reference for the rejections. Pages 19-97 of the Request detail out proposed substantial new questions of patentability in light of the combination of the five references cited above.

Prosecution History

3) The Lekhtman patent was assigned serial number 07/895,936. During prosecution, the application was allowed with no reasons for allowance after two separate rejections by the examiner. However, several amendments were made to the claims during prosection, and several distinctions in the claim language were brought up in responses by the applicant to examiner's rejections. These purported distinctions are utilized below in determining a substantial new question of patentability. None of the five references in the currently filed request were previously discussed by the examiner or applied to claims 1-16 in the prosecution history of the Lekhtman patent.

Substantial New Question of Patentability

4) For purposes of determination, independent claim 1 is a representative claim. The italicized sections of claim 1 below are utilized by the examiner to show how specific teachings of the proposed references create a substantial new question of patentability. These claim sections were either added in by applicant during amendments to the originally filed claims or argued as distinguishable over the prior art of record at the time of the original prosecution.

Claim 1:

A heart rate monitor for use by a user in association with exercise apparatus and/or exercise procedures, comprising;

an elongate member;

electronic circuitry including a difference amplifier having a first input terminal of a first polarity and a second input terminal of a second polarity opposite to said first polarity;

said elongate member comprising a first half and a second half;

a first live electrode and a first common electrode mounted on said first half in spaced relationship with each other;

a second live electrode and a second common electrode mounted on said second half in spaced relationship with each other;

said first and second common electrodes being connected to each other and to a point of common potential;

said first live electrode being connected to said first terminal of said difference amplifier and said second live electrode being connected to said second terminal of said difference amplifier;

a display device disposed on said elongate member;

wherein, said elongate member is held by said user with one hand of the user on said first half contacting said first live electrode and said first common electrode, and with the other hand of the user on said second half contacting said second live electrode and said second common electrode;

whereby, a first electromyogram signal will be detected between said first live electrode and said first common electrode, and a second electromyogram signal, of substantially equal magnitude and phase to said first electromyogram signal will be detected between said second live electrode and said second common electrode;

so that, when said first electromyogram signal is applied to said first terminal and said second electromyogram signal is applied to said second terminal, the first and second electromyogram signals will be subtracted from each other to produce a substantially zero electromyogram signal at the output of said difference amplifier;

and whereby a first electrocardiograph signal will be detected between said first live electrode and said first common electrode and a second electrocardiograph signal, of substantially equal magnitude but of opposite phase to said first electrocardiograph signal will be detected between said second live electrode and said second common electrode;

so that, when said first electrocardiograph signal is applied to said first terminal and said second electrocardiograph signal is applied to said second terminal, the first and second electrocardiograph signals will be added to each other to produce a non-zero electrocardiograph signal at the output of said difference amplifier;

means for measuring time intervals between heart pulses on detected electrocardiograph signal;

means for calculating the heart rate of said user using said measure time intervals;

said means for calculating being connected to said display device;

whereby, the heart rate of said user is displayed on said display device.

Fujisaki

5) The Fujisaki reference describes a heart pulse rate measuring system including four electrodes coupled to a differential amplifier. The Request shows that Fujisaki teaches *electronic circuitry including a difference amplifier having a first input terminal of a first polarity and a*

second input terminal of a second polarity opposite to said first polarity (Figure 3, label # 31 and col. 3 lines 3-10, whereby a differential amplifier is utilized)*; a first live electrode and a first common electrode mounted on said first half in spaced relationship with each other and a second live electrode and a second common electrode mounted on said second half in spaced relationship with each other* (col. 3 lines 3-13 and Figure 2, whereby each side of the device has two electrodes, a common and an active)*;means for measuring time intervals between heart pulses on detected electrocardiograph signal* (Figure 3, label #'s 31, 32, 33, and col. 3 lines 17-19, whereby a threshold limiter is utilized)*; means for calculating the heart rate of said user using said measure time intervals* (Figure 3 and col. 3 lines 28-38, whereby a microprocessor is utilized)*; said means for calculating being connected to said display device whereby, the heart rate of said user is displayed on said display device* (Figure 1 and col. 4 lines 52-59, whereby heart rate is displayed on an LCD).

The Fujisaki reference was not previously discussed by the examiner nor applied to claims 1-16 in the prior examination of the patent as discussed above.

It is agreed that the consideration of Fujisaki raises a SNQ as to claims 1-16 of the Lekhtman patent as pointed out above. There is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not these claims are patentable.

Accordingly, Fujisaki alone raises a substantial new question of claims 1-16, which question has not been decided in a previous examination of the Lekhtman patent nor was there a final holding of invalidity by the Federal Courts regarding the Lekhtman patent.

Biosig, The "E" Factor Book, Charnitski, and The Biophysical Measurements Book

6) These four references were cited by Requester as supporting Fujisaki in alternative obviousness rejections of claim 1, as well as proposed teachings for many dependent claims in Lekhtman. Examiner agrees that many of claims 1-16 of Lekhtman, as mapped out in the Request on pages 38-97, appear to be read on by the combination of the four references listed above.

None of these four references were previously discussed by the examiner nor applied to claims 1-16 in the prior examination of the patent as discussed above.

It is agreed that the consideration of Biosig, The "E" Factor Book, Charnitski, and The Biophysical Measurements Book, in combination with the Fujisaki reference above, raises a SNQ as to claims 1-16 of the Lekhtman patent as pointed out in the claim mappings given in the Request at pages 38-97. There is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not these claims are patentable.

Accordingly, these references raise a substantial new question of claims 1-16, which question has not been decided in a previous examination of the Lekhtman patent nor was there a final holding of invalidity by the Federal Courts regarding the Lekhtman patent.

Scope of Reexamination

7) Claims 1-16 will be reexamined as requested in the Request.

Conclusion

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extension of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 5,337,753 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

All correspondence relating to this ex parte reexamination proceeding should be directed as follows:

By U.S. Postal Service Mail to:

Mail Stop Ex Parte Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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EFS-Web offers the benefit of quick submission to the particular area of the Office that needs to act on the correspondence. Also, EFS-Web submissions are "soft scanned" (i.e., electronically uploaded) directly into the official file for the reexamination proceeding, which offers parties the opportunity to review the content of their submissions after the "soft scanning" process is complete.

Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

/Alexander J Kosowski/

Primary Examiner, Art Unit 3992

ESK

United States Patent [19]

Fujisaki et al.

[11] **4,444,200**

[45] **Apr. 24, 1984**

[54] **HEART PULSE RATE MEASURING SYSTEM**

[75] Inventors: **Iwao Fujisaki,** Ichikawa; **Shuichi Kosuge,** Tama; **Syuu Ogawa,** Kasukabe; **Kimihiko Sato,** Funabashi; **Toshimi Soeda,** Tokyo, all of Japan

[73] Assignee: **Senoh Kabushiki Kaisha,** Tokyo, Japan

[21] Appl. No.: **299,578**

[22] Filed: **Sep. 4, 1981**

[51] **Int. Cl.**³ **A61B 5/04**

[52] **U.S. Cl.** **128/706**

[58] **Field of Search** 128/639, 690, 702, 706, 128/707, 708, 710

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,802,698	4/1974	Burian et al.	128/707
3,868,947	3/1975	Holsinger	128/639
4,007,731	2/1977	Griffiths et al.	128/710
4,083,366	4/1978	Gombrich et al.	128/706
4,221,223	9/1980	Linden	128/706
4,224,948	9/1980	Cramer et al.	128/690
4,237,903	9/1980	Hofmann	128/708
4,319,581	3/1982	Cutter	128/707

Primary Examiner—William E. Kamm

Attorney, Agent, or Firm—Lowe, King, Price & Becker

[57] **ABSTRACT**

A heart pulse rate measuring system comprises a casing, a pair of rod-shaped grip sensors extending outwardly from the opposite sides of the casing for sensing a heart pulse signal, and an electric circuit for calculating a heart pulse rate from the sensed heart pulse signal. Each of the grip sensors is composed of two conductive cylindrical electrodes arranged in an axially aligned relationship and electrically insulated from each other for obtaining a pulse rate utilizing the potentials at four points in a user's body. The electric circuit includes a differential amplifier, having a ground connection to one of the two electrodes of each sensor and two inputs for the remaining electrodes. A filter is used to eliminate noise from the output of the differential amplifier, and a computer calculates the heart rate from the output of the filter. Additionally, an AC-DC converter is connected between the differential amplifier and the computer for providing a DC signal to the computer when an output is provided by the differential amplifier. The computer responds to a predetermined DC level by starting a display indication of heart pulse rate. A timer is provided for use of the system with an exercise device and an alarm is activated at the expiration of the preset exercise time or if pulse rate deviates beyond upper or lower limits preset therefor. A printer provides a printout of time and/or pulse rate at predetermined time intervals.

5 Claims, 3 Drawing Figures

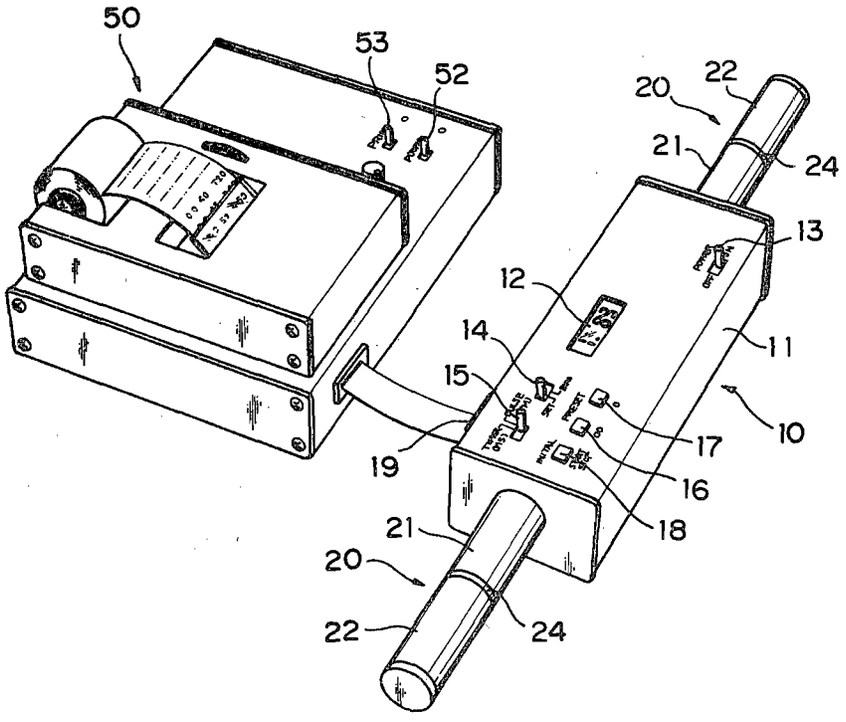

EXHIBIT 4

FIG. 1

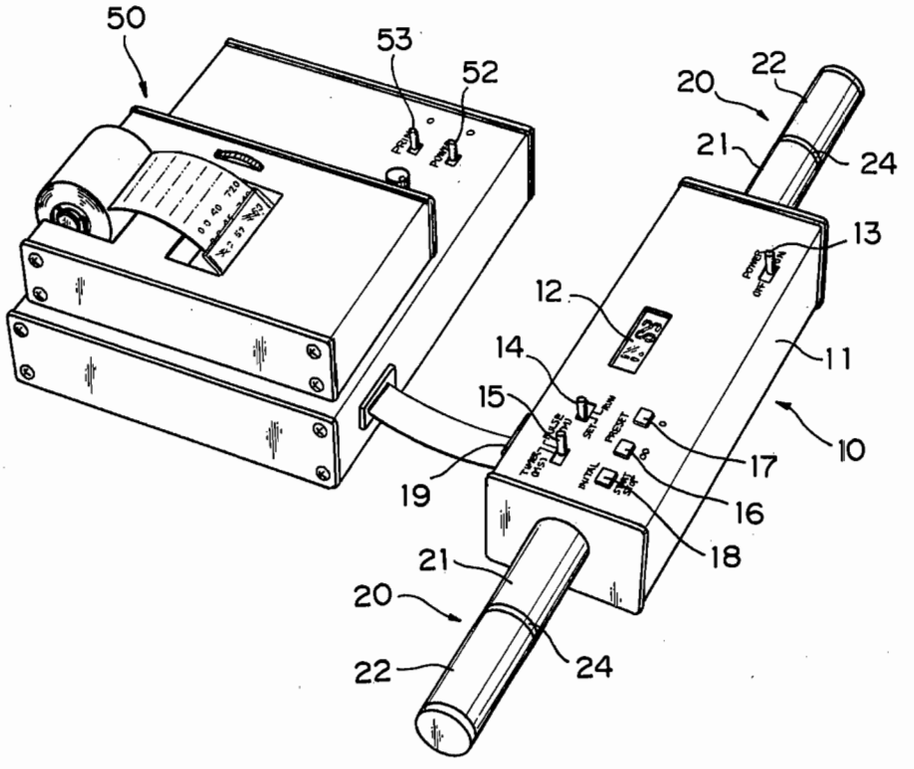

EXHIBIT 4

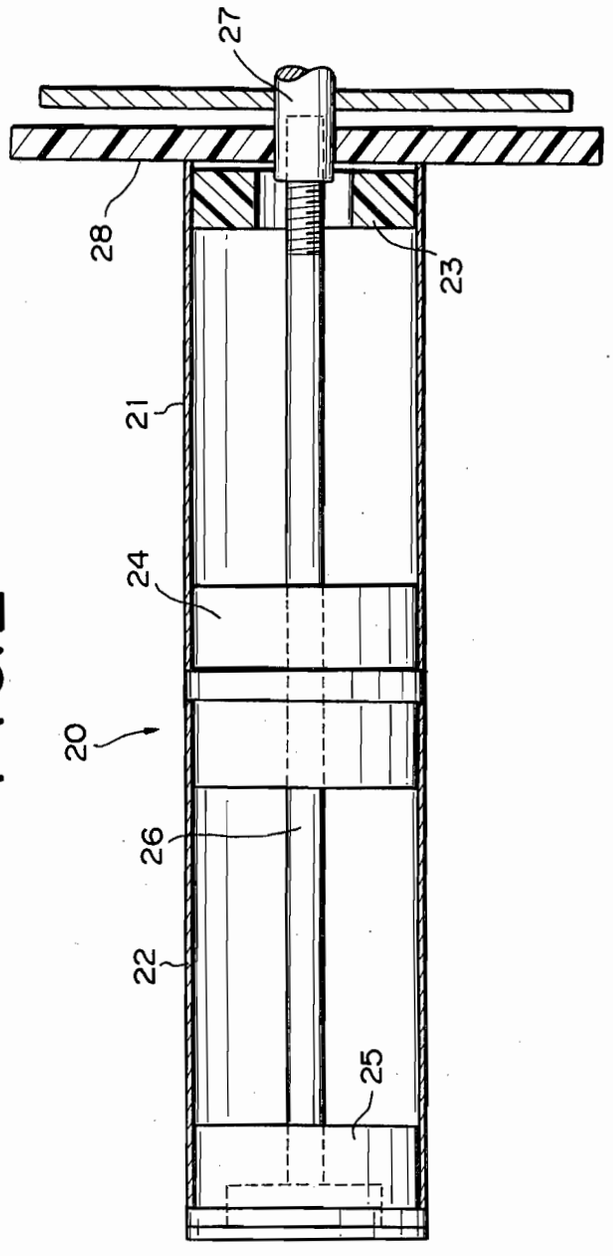

FIG.2

EXHIBIT 4

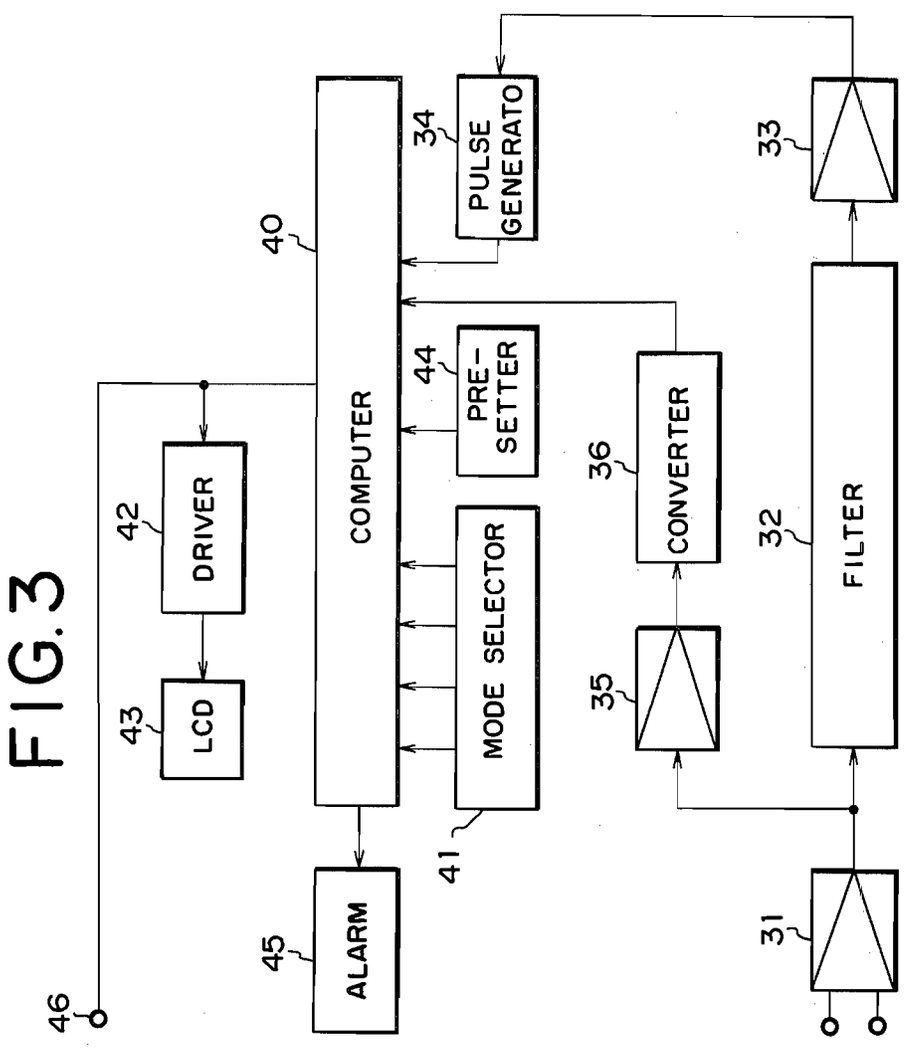

FIG. 3

EXHIBIT 4

HEART PULSE RATE MEASURING SYSTEM

BACKGROUND OF THE INVENTION

This invention relates to a system for measuring heart pulse rate and, more particularly, to such a heart pulse rate measuring system having a pair of grip sensors adapted to be gripped with both hands for sensing heart pulse signals.

During an exercise, skeletal muscles are used and heart beats become faster so that more blood is pumped to replace nutrients in the skeletal muscles. For finding out how much exercise a person's body can take or his fitness level, it is important to get an accurate reading of his heart function. Heart beats produce a heart pulse signal which is relatively independent of person's movements, external temperature and other environment conditions. In order to get information on such heart function, it is common practice to measure heart pulse rate based upon such a heart pulse signal by using heart pulse signal sensors attached directly on several points of a person's body near his heart and connected through long wires to a separate measuring unit. However, this has been found to be insufficient in heart pulse rate measuring accuracy penalty and inconvenience attendant upon attachment and detachment of the sensors from the person's body.

The present invention provides a simple heart pulse rate measuring system which can make an accurate indication of heart pulse rate in a very short time simply by gripping grip sensors with both hands.

SUMMARY OF THE INVENTION

There is provided, in accordance with the present invention, a heart pulse rate measuring system which comprises a casing, a pair of rod-shaped grip sensors extending outwardly from the opposite sides of the casing for sensing a heart pulse signal, an electric circuit contained in the casing for calculating a heart pulse rate from the sensed heart pulse signal, and a display unit associated with the electric circuit for displaying the calculated heart pulse rate. Each of the grip sensors is composed of two conductive cylindrical electrodes arranged in axially aligned relationship and electrically insulated from each other. The electric circuit includes a differential amplifier having inputs from the grip sensors for amplifying the difference between the heart pulse signals applied thereto from the grip sensors, a filter circuit having an input from the differential amplifier for eliminating noises from the heart pulse signal applied thereto from the differential amplifier, a pulse generator having an input from the filter circuit for generating a rectangular pulse signal corresponding to the heart pulse signal applied thereto from the filter circuit, and a digital computer for counting pulses of the pulse signal fed thereto from the pulse generator and calculating a heart pulse rate.

Preferably, the electric circuit includes an alarm unit, and means for presetting upper and lower limit values for the calculated heart pulse rate into the digital computer. The digital computer is adapted to cause the alarm unit to provide a warning alarm when the calculated heart pulse rate exceeds the preset upper limit value or falls below the preset lower limit value.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be described in greater detail by reference to the following description taken in connection with the accompanying drawings, in which:

FIG. **1** is a perspective view showing one embodiment of a heart pulse rate measuring system made in accordance with the present invention, the system comprising a center unit and a digital printer;

FIG. **2** is a sectional view showing one grip sensor used in the heart pulse rate measuring system of FIG. **1**; and

FIG. **3** is a block diagram showing an electric circuit used in the center unit.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to FIG. **1**, there is illustrated one embodiment of a heart pulse rate measuring system made in accordance with the present invention. The system comprises a center unit **10** and a digital printer **50** associated with the center unit **10**.

The center unit **10** comprises a casing **11** formed in its upper surface with a window **12** through which a liquid crystal display is exposed to view. The casing **11** supports on its upper surface a power switch **13**, first and second mode selection switches **14** and **15**, upper and lower digit preset buttons **16** and **17**, and an initial button **18**. The first mode selection switch **14** is movable between its RUN and SET positions, and the second mode selection switch **15** is movable between its PULSE and TIMER positions. The upper digit preset button **16** is used to select two upper digits and the lower digit preset button **17** is used to select one lower digit. The initial button **18** is used to register the selected numbers in a memory of a digital computer to be described later and also to start a timer included in the digital computer. The casing **11** supports on its side surface a connector **19** for connection to the digital printer **50**. A pair of rod-shaped grip sensors **20** extends outwardly from insulating panels **28** secured on the opposite end surfaces of the casing **11**.

As shown in FIG. **2**, each of the left- and right-hand grip sensors **20** has inner and outer cylindrical electrodes **21** and **22** which are made of a conductive material, such as for example, stainless steel. The inner electrode **21** is bonded at its inner end on a support ring **23** and at its outer end on one shoulder of a spacer **24**. The outer electrode **22** is bonded at its inner end on the other shoulder of the spacer **24** and at its outer end on the shoulder of an end cap **25**. A bolt **26** extends through the end cap **25**, the spacer **24**, and the support ring **23** and threadedly engaged with a nut **27** secured in the insulating plate **28** so as to secure them to the end surface of the casing **11**. The support ring **23**, the spacer **24**, and the end cap **25** are made of an insulating material, such as for example, plastic. In such a manner, the inner and outer cylindrical electrodes **21** and **22** are arranged in axially aligned relationship and electrically insulated from each other. The inner and outer electrodes **21** and **22** are connected to an electric circuit to be described later through separate electric cords extending therefrom into the casing **11**.

When a person grips the left- and right-hand grip sensors **20** with both hands, preferably with the center of his palms covering the spacers **24** between the inner and outer electrodes **21** and **22**, the inner and outer electrodes **21** and **22** catch heart pulse signals caused by

EXHIBIT 4

heart beats together with AC hum and human body hum (hereinafter referred merely to as noises).

Referring to FIG. 3, there is illustrated an electric circuit, which is generally designated at 30, contained in the casing 11 of the center unit 10. The electric circuit 30 includes a differential amplifier 31 which has its one input coupled to the outer cylindrical electrode 22 of the left-hand grip sensor 20, the other input thereof being connected to the outer cylindrical electrode 22 at the right-hand grip sensor 20. The inner cylindrical electrodes 21 of the left- and right-hand grip sensors 20 are coupled to the ground terminal of the differential amplifier 31. The differential amplifier 31 amplifies the difference between the voltages applied to the inputs thereof. This is effective to reduce the noises introduced into the heart pulse signals fed to the differential amplifier 31 from the grip sensors 20. The output of the differential amplifier 31 is then coupled to a filter circuit 32 which further reduces or eliminates the noises still included in the heart pulse signal from the differential amplifier 31. The output of the filter circuit 32 is fed through an amplifier 33 to a pulse generator 34 which generates a rectangular pulse signal related to the pulse signal from the amplifier 33. That is, the pulse generator 34 provides a train of pulses corresponding to the heart beats of the person.

The electric circuit 30 also comprises a digital computer 40 operable in several modes one of which is selectively set by a mode selector 41 comprised of the first and second mode selection switches 14 and 15. If the first mode selector switch 14 is in its RUN position and the second mode selection switch 15 is in its PULSE position, the digital computer 40 is placed in a pulse rate measuring mode to count the pulses from the pulse generator 34 and calculate the heart pulse rate, which corresponds to the rate of heart beats occurring in a minute, within five or six seconds. The digital computer 40 provides a command signal to a driver 42 which thereby makes an indication of the calculated heart pulse rate on a liquid crystal display 43. When the first mode selector switch 14 is in its RUN position and the second mode selection switch 15 is in its TIMER position, the digital computer 40 operates as a timer and indicates, on the liquid crystal display 43, the elapsed time at every second after the initial button 18 is depressed once. When the initial button 18 is depressed twice, the time display stops and keeps on displaying the value. When the initial button 18 is depressed for the third time, the time indication returns to zero.

The digital computer 40 may be associated with a presetter 44, which is comprised of the upper and lower digit present buttons 16 and 17 and the initial button 18, for presetting upper and lower limit values for calculated heart pulse rate. The upper limit value may be preset at the maximum heart pulse rate above which it will become dangerous to continue to exercise. The lower limit value may be selected at the minimum heart pulse rate below which the exercise will not achieve the desired effects. The digital computer 40 is placed in its first preset mode of operation if the first mode selection switch 14 is placed in its SET position and the second mode selection switch 15 is placed on its PULSE position. Under this condition, the upper and lower values can be preset separately by continuously depressing the upper and lower digit preset buttons 16 and 17 until desired numbers for the upper and lower limit values appear on the liquid crystal display 43 and then depressing the initial button 18 to register the numbers in the memory of the digital computer 40.

The digital computer 40 is placed in its second preset mode of operation when the first mode selection switch 14 is in its SET position and the second mode selection switch 15 is in its TIMER position. Under this condition, a desired exercise time can be preset by continuously depressing the upper and lower digit preset buttons 16 and 17 until desired numbers for the desired exercise time appear on the liquid crystal display 43 and thereafter depressing the initial button 18 to register the number in the memory of the digital computer 40.

When the calculated pulse rate exceeds the preset upper limit value, the calculated pulse rate falls below the preset lower limit value, or the elapsed exercise time exceeds the preset value, the digital computer 40 provide a warning signal to an alarm 45 which thereby provides a warning alarm such as sounding a buzzer.

The output of the differential amplifier 31 is also coupled through a tough-sensor amplifier 35 to an AC-DC converter 36 and hence to the digital computer 40. The AC-DC converter 36 converts the AC signal from the differential amplifier 31 into a corresponding DC signal. In response to the DC signal from the AC-DC converter 36, the digital computer 40 makes a determination as to whether or not any person grips the grip sensors 20 with his both hands. This may be used to start operation of the digital computer 40 to make a heart pulse rate indication when it detects any person gripping the grip sensors 20.

The command signal from the digital computer 40 to the driver 42 is also coupled to an output terminal 46 for connection to the digital printer 50. The digital printer 50 contains therein a timer (not shown) for printing out, on a tape 51, the values displayed on the liquid crystal display 43 together with the elapsed exercise time provided by the timer at a predetermined time interval. The reference numeral 52 designates a power switch, and the numeral 53 designates a print start switch.

The operation of the heart pulse rate measuring system of the present invention will now be described. Assuming first that a person desires to know his heart pulse rate during or immediately after an exercise, he turns the first mode selection switch 14 to its RUN position and the second mode selection switch 15 to its PULSE position. When he grips the grip sensors 20 with his both hands, heart pulse signals are applied to the inputs of the differential amplifier 31. The output of the differential amplifier 31 is applied through the filter circuit 32 and the amplifier 33 to the pulse generator 34. The heart pulse signal applied from the amplifier 33 to the pulse generator is free from noises. The pulse generator 34 converts the heart pulse signal into a corresponding rectangular pulse signal which is fed to the digital computer 40. The digital computer 40 counts the pulses from the pulse generator 34 and calculates a heart pulse rate within five or six seconds. The calculated heart pulse rate is displayed on the liquid crystal display 43 through the driver 42. The calculated heart pulse rate is also printed out by the digital printer 50 with the elapsed exercise time at a predetermined time interval.

If upper and lower limit values for heart pulse rate and a desired value for elapsed exercise time are previously preset by the use of the presetter 44, the alarm 45 will provide a warning alarm when the calculated pulse rate exceeds the preset upper limit value, the calculated pulse rate falls below the preset lower limit value, or the elapsed exercise time exceeds the preset value.

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There has been provided, in accordance with the present invention, a simple heart pulse rate measuring system capable of making an accurate indication of heart pulse rate in a very short time simply by gripping grip sensors with both hands. While the present invention has been described in conjunction with a specific embodiment thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

What is claimed is:

1. An apparatus for measuring the heart pulse rate of a user, comprising:

(a) a casing;

(b) a pair of rod-shaped grip sensors extending outwardly from the opposite sides of said casing, each of said grip sensors being composed of first and second cylindrical conductive electrode means arranged in axially aligned relationship and electrically insulated from each other for sensing a heart pulse signal utilizing potentials at four points on the user's body, obtained when the user grips both of said first and second electrode means of each said grip sensor with one hand; and

(c) an electric circuit contained in said casing, said electric circuit including:

a differential amplifier having a common ground electrically connected to said first conductive electrode means of each of said grip sensors and a pair of additional inputs respectively electrically connected to said second electrode means of each of said grip sensors for providing an output corresponding to a difference between the heart pulse signals from said grip sensors;

a filter circuit means having an input from said differential amplifier for eliminating noises from the heart pulse difference signal applied thereto from said differential amplifier;

a digital computer means responsive to an input from said filter circuit means for calculating a heart pulse rate;

a display means associated with said digital computer means for displaying the calculated heart pulse rate;

an AC-DC converter connected between said differential amplifier and said digital computer means for converting an AC signal from said differential amplifier into a corresponding DC signal; and

said digital computer means including means sensitive to the DC signal from said AC-DC converter for causing said display means to start displaying the calculated heart pulse rate thereon.

2. The apparatus of claim 1, wherein said electrical circuit includes an alarm unit connected to said digital computer means and means for presetting upper and lower limit values for the calculated heart pulse rate into said digital computer means, and wherein said digital computer means includes means for causing said alarm unit to provide a warning alarm when the calculated heart pulse rate exceeds the preset upper limit value or falls below the preset lower limit value.

3. The apparatus of claim 2, wherein said electric circuit includes means for presetting a desired exercise time into said digital computer means, and wherein said digital computer means includes means for causing said alarm unit to provide a warning alarm when the elapsed exercise time exceeds the preset exercise time.

4. The apparatus of claim 1, which further comprises a digital printer means associated with said digital computer means for printing out the calculated heart pulse rate at predetermined time intervals.

5. The apparatus of claim 4, wherein said digital printer means contains a timer for printing out the calculated heart pulse rate together with elapsed exercise time.

* * * * *

EXHIBIT 4

Exhibit 6 to the Request for Ex Parte Re-examination of

In re Patent No: 5,337,753

Issued: Aug. 16, 1994

Filed: Jun. 9, 1992

Applicant: Gregory Lekhtman

Title: Heart Rate Monitor

Everything the modern athlete should know: training regimens, special diets and diet aids, state-of-the-art equipment, sports psychology, drugs and drug testing, and much, much more!

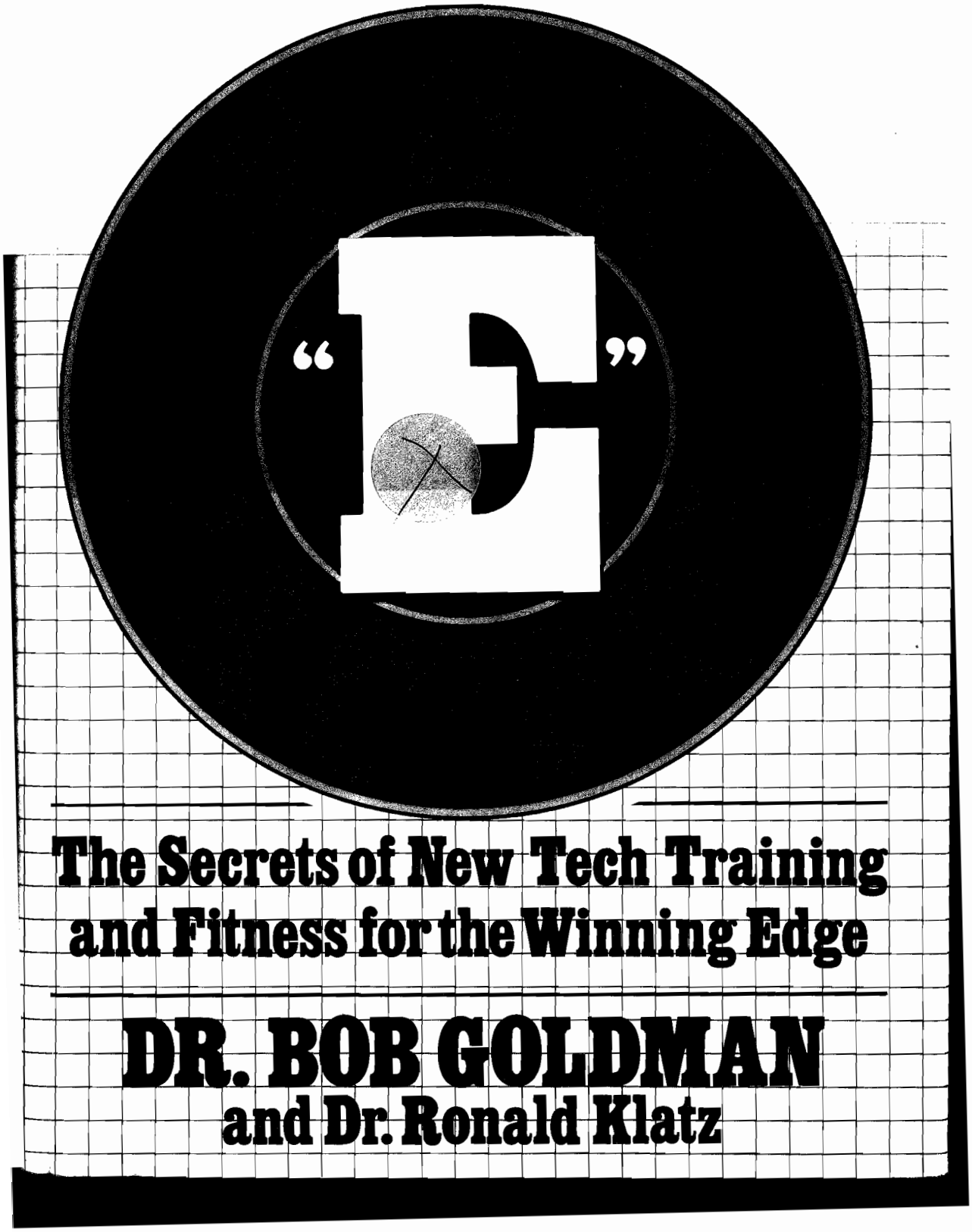
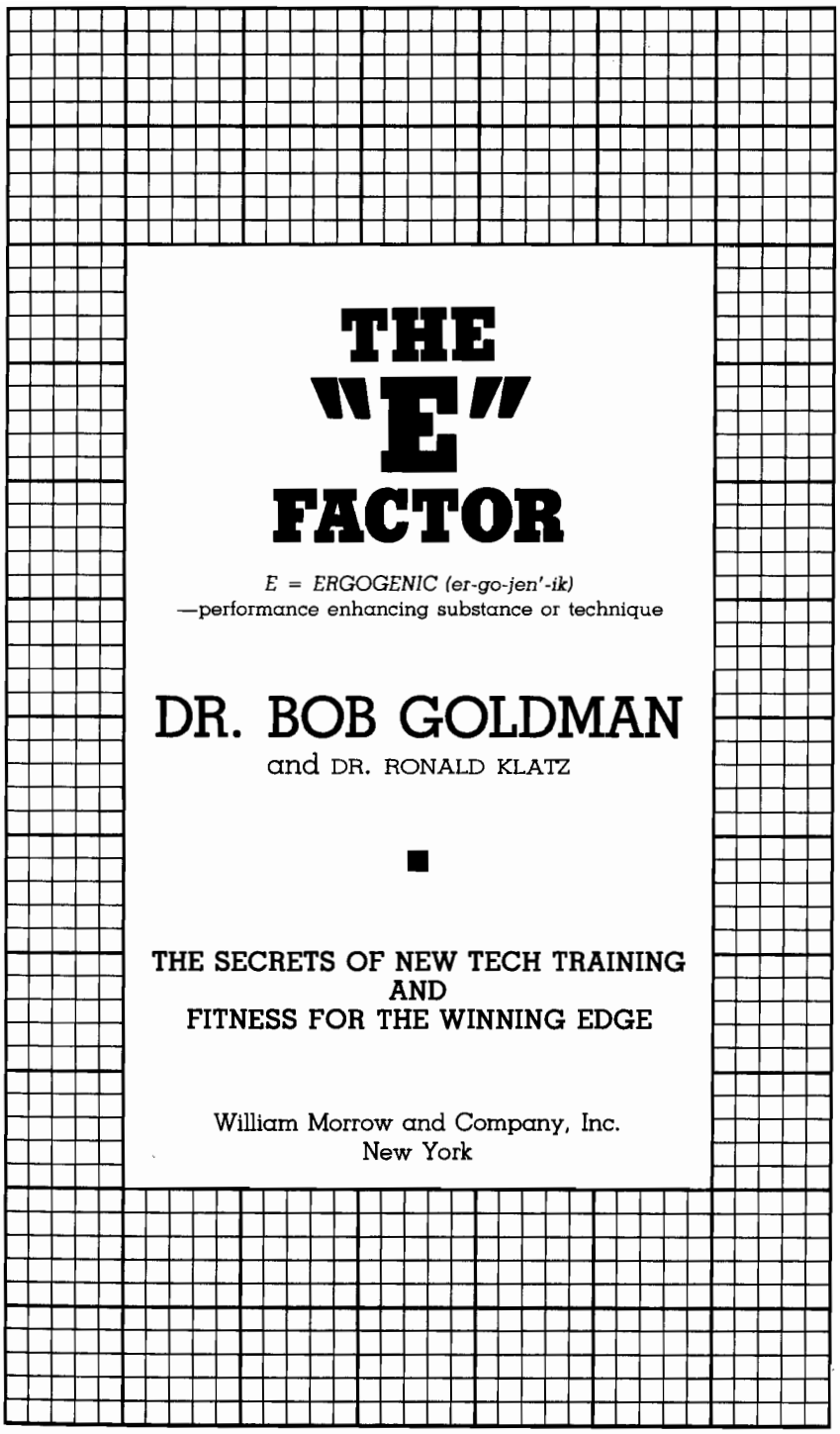


EXHIBIT 6



THE "E" FACTOR

E = ERGOGENIC (er-go-jen'-ik)
—performance enhancing substance or technique

DR. BOB GOLDMAN
and DR. RONALD KLATZ

■

THE SECRETS OF NEW TECH TRAINING
AND
FITNESS FOR THE WINNING EDGE

William Morrow and Company, Inc.
New York

EXHIBIT 6

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EXHIBIT 6

CHAPTER XIX

HIGH-TECH PULSE MONITORING*

The volume of blood pumped by the heart per minute is proportional to heart rate and stroke volume and is called cardiac output. Stroke volume is the amount of blood pumped with each beat of the heart, and is proportional to the size of the heart. The cardiac output is an essential parameter for evaluation of cardiovascular exertion. The heart receives blood at a low pressure and sends it out at a high pressure. The relaxed state between beats of the heart is called diastole. Contraction of the heart is called systole. Because of mechanical restraints in the heart's ventricle construction, heart rates above 180 BPM make performance of the heart inefficient. In order to maintain cardiovascular fitness, the training zone of the heart rate should be maintained below the maximum heart rate, which equals 220 minus the age and determines ineffective dangerous heart rate. Usually the average training heart rate is from 70 to 85 percent of the maximum heart rate and is called the target zone (Figure 1).

Heart rate is a medical term for *pulse*. It is not a stable parameter, and is largely under reflex control by the autonomic nervous system. Cardioaccelerator and cardioinhibitor centers cause the increase and decrease of the heart rate. The stimulation of any cutaneous nerve will elicit a change in it. Pain, heat, cold, blood pressure, touch, joy, exhilaration, fear, anxiety, respiration, and any other activity may cause a variation in the heart rate. Any body or brain demand for oxygen will affect the cardiac output, and in turn will change the heart rate and its regularity. It is well known that stimulation of certain areas of the brain can reproduce the pattern of cardiac re-

*The material on pages 240–247 was contributed by Gregory Lekhtman.

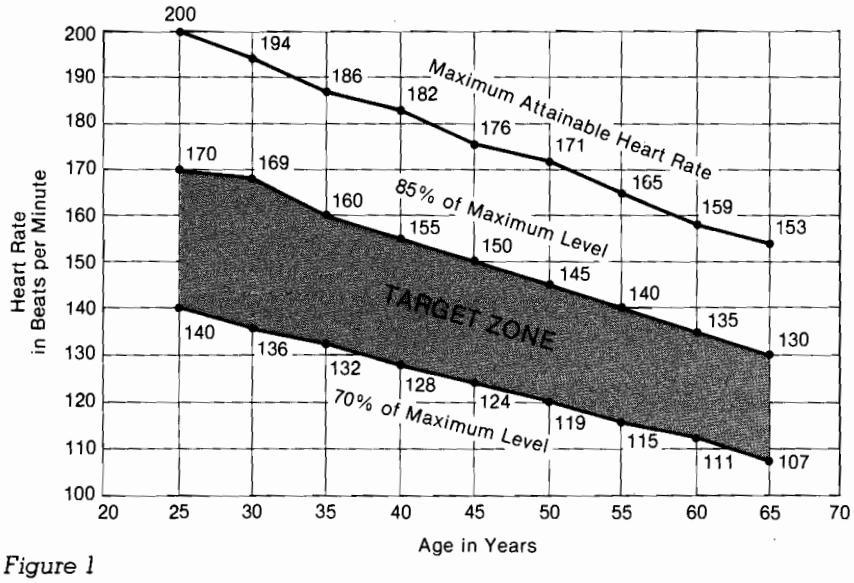

Figure 1

sponse associated with physiological activities such as exercise. In other words, the physiological condition of the individual is an important factor in heart rate. The fitness level can be evaluated just by analyzing the instant changes in heart rate when going from a sitting to a standing position. The fluctuation of the heart rate is sometimes more important than heart rate itself, and should always be monitored during sports training.

The following techniques are used to monitor heart rate:

1 Manual pulse-taking, based on intervals of 10–15 seconds, can produce an average error from +16 to −18 beats per minute, and is totally inaccurate in estimating the fluctuation of the heart rate in response to exercise or psychological stress.
2 Photo-electric pickups from earlobe or finger sensors, or other techniques using peripheral blood pulse pickup, are also inaccurate, because there is inconsistent time delay between heart contraction and propagation of the blood pulse to the periphery (Figure 2). This delay is a function of the condition of the blood vessels, body temperature, gravitation, and acceleration forces during physical activities. Another problem in this method is susceptibility to the mechanical interference from body movement, and that is why this method cannot be used for accurate pulse monitoring, especially during physical activity. Nevertheless, some manufacturers and distributors of devices using this method of pickup were successful in penetrating the fitness market.

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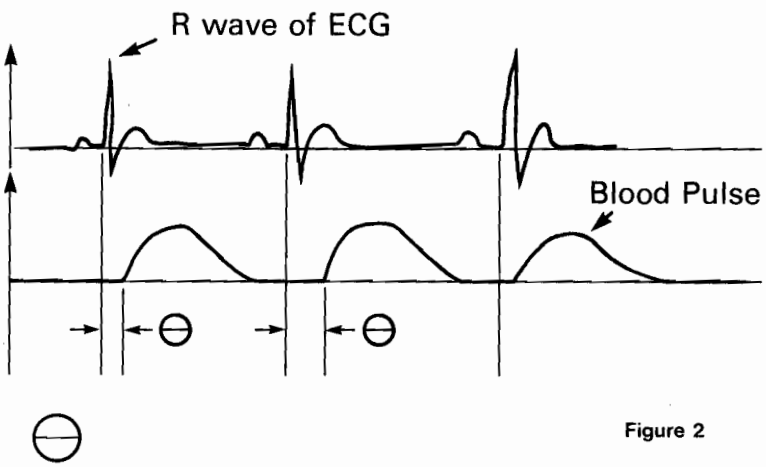


Figure 2

Time delay between heart contraction and peripheral blood pulse.

3 ECG pickup from the chest or peripheries is the most reliable and most accurate method of pickup because each R wave (represented by the "spike" portion of the printout) of ECG signal represents precise timing in heart contraction and is totally unaffected by physical conditions of the body, gravity, and physical movement. The technology involved in monitoring ECG without special preparation of the skin is very sophisticated, and that is why many manufacturers try to avoid this method.

The following techniques are used to calculate the heart rate:

1 Average calculation is the oldest and best-known technique. Average pulse calculations are done by counting the number of pulses per given time.

For example:

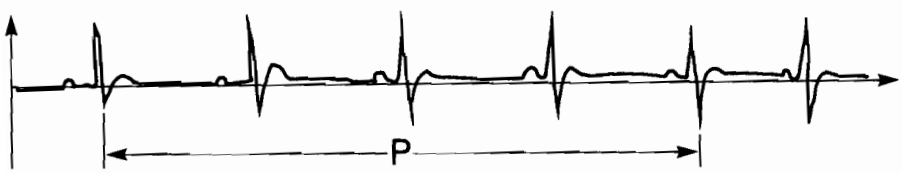


Figure 3

P = Time; N = number of pulses; BPM = Beats/Min.
Example: N=5; P=6 seconds = 1/10 minute = .1 min.
BPM = N/P = 5/.1 min. = 50 BPM

EXHIBIT 6

The longer the period, the less fluctuation of the heart rate will be shown. But the calculation will not represent the true picture, especially for people with unstable heart rates, and also athletes with fast recovery time; i.e., if your average is based on 15-second intervals, the calculation of heart rate will show, for instance, 150 beats per minute, but the trained athlete's actual pulse will recover at this time to 120 beats per minute. The discrepancy of 30 beats per minute occurs because of this technique of calculation.

The average method of calculation doesn't show the changes in time between one beat of the heart to another (fluctuation), and doesn't represent the true picture of the heart's response to exercise, stress, and environment.

In the past, when the electrocardiogram and beat-to-beat measurements of the heart rate were not available, heart rate was perceived as a stable parameter. This error is still common, even among those medical and fitness professionals who have never studied the physiology of the heart.

2 Beat-to-beat calculations are done by counting the time between two pulses and converting this time into BPM using the formula BPM = 60.

For example:

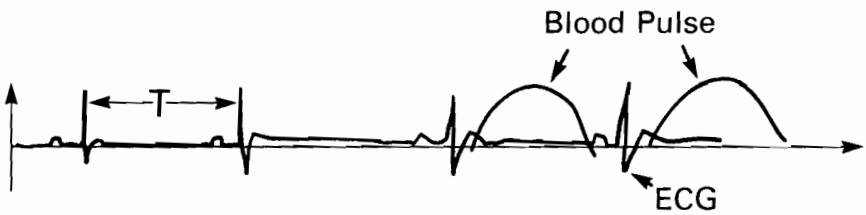


Figure 4

T = Time between pulses in seconds
T = 1 second; BPM = 60/1 = 60 BPM
T = 0.983 second; BPM = 60/0.983 = 61 BPM

This technique is the most accurate and represents the true picture of the heart rate and heart-rate response. Beat-to-beat calculation cannot be performed with earlobe or finger detectors because they pick up the mechanical pulse of the blood wave, which is generated by heart contractions, but this wave is 40 times wider than the R wave of the EKG, and the fronts of it cannot be identified. Some monitors combine beat-to-beat calculation with computer averaging based on 4 or 6 beats.

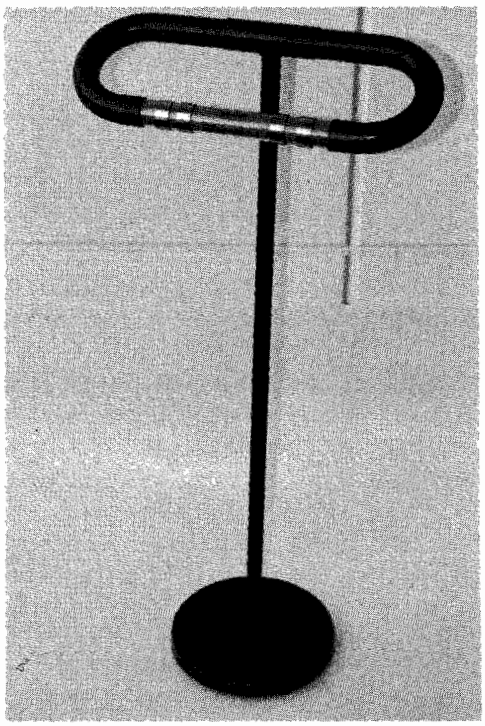
Based on evaluation of the techniques of pickup calculation, let me present a verbal picture of the heart-rate monitor that would be most valuable for sports training:

1 The heart-rate monitor should be a guide in exercise, a personal motivator, a preventive diagnostic tool, a biofeedback instrument, all in one. This is why it should be ECG-type beat-to-beat, or a maximum 4–6 beats average.
2 No alarms or beeping features should be presented to the user, because, as was mentioned before, the heart rate is altered by any psychological stimuli. The heart monitor should be a passive measuring device only.
3 The heart-rate monitors should be "user friendly," which means that any multiple-functions knobs, dials, and push buttons will distract the person from concentrating on exercise and will produce psychological stress, which results in a change in the heart-rate response.

PULSE METERS

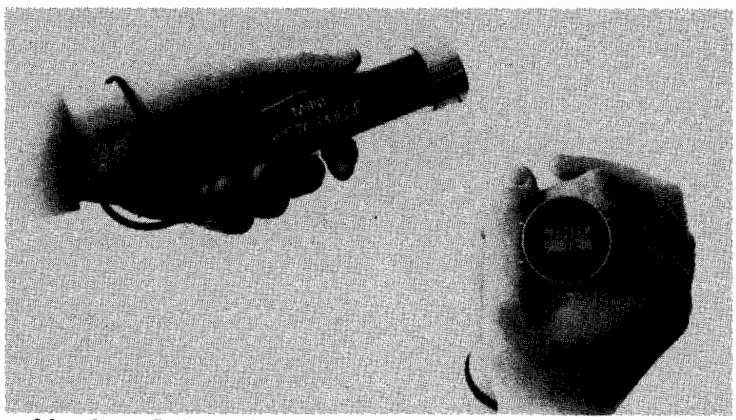
Biosig

Biosig Instruments has developed a variety of heart-rate monitors for professional and home use. All the monitors use the ECG principle of pickup from the hands and chest. The type of calculation is beat-to-beat or 2-, 4-, and 6-beat average.



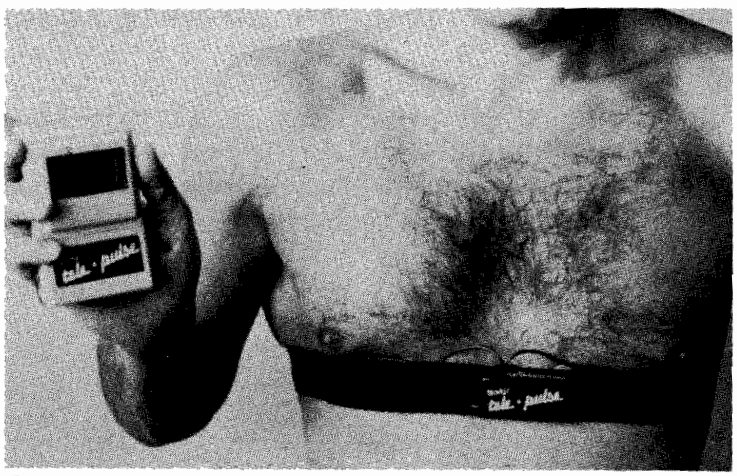
Insta-Pulse 105 on floor stand

The *Insta-Pulse 105* looks like a rally baton, and can be used during running and other activities. It has a 4-beat average ECG pickup from the hand; it is watertight and comes with an optional wall bracket or floor stand.



Mini Insta-Pulse 107

The *Mini Insta-Pulse 107* has similar functions, but is half the size and features a 2-beat ECG pickup.



Tele-Pulse 801

The *Tele-Pulse 801* wireless pulse meter uses a small transmitter with a chest-belt ECG pickup through the short. It transmits heart rate by radio up to 30 feet away from the receiver, which can be mounted on treadmills, rowing machines, etc.

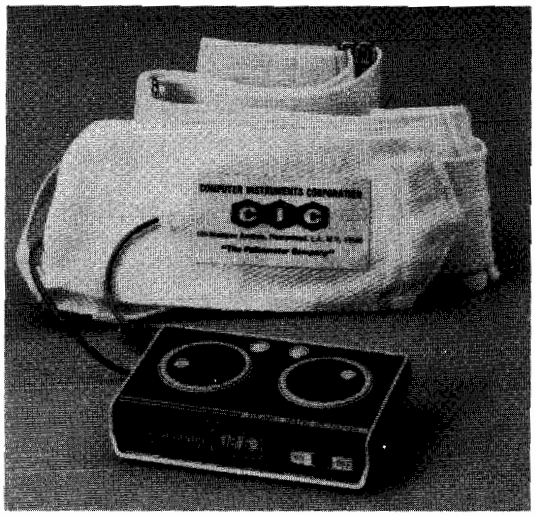
The *Insta-Pulse 302* bicycle pulse meter fits on all types of exercise bikes. It has ECG pickup from the handlebars and a 6-beat average.

Insta-Pulse 302

Biosig Instruments
5471 Royal Mountain Ave.
Montreal, Quebec
Canada HY8 153
514-733-3362

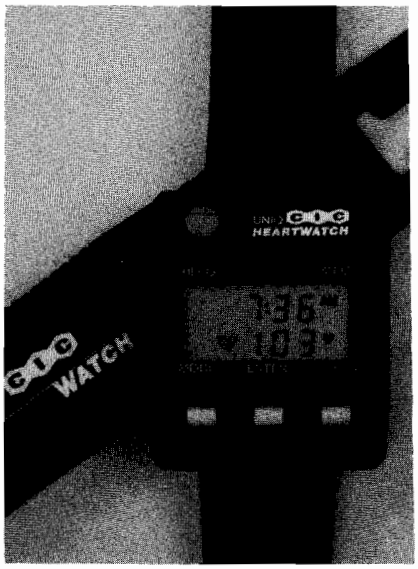
Computer Instruments Corp. (CIC)

The *Exersentry* heart-rate monitor operates through skin moisture and requires no messy gels. The lightweight harness is placed around the chest so that body motion is not hindered. The electrodes are built into the chest belt and will record from

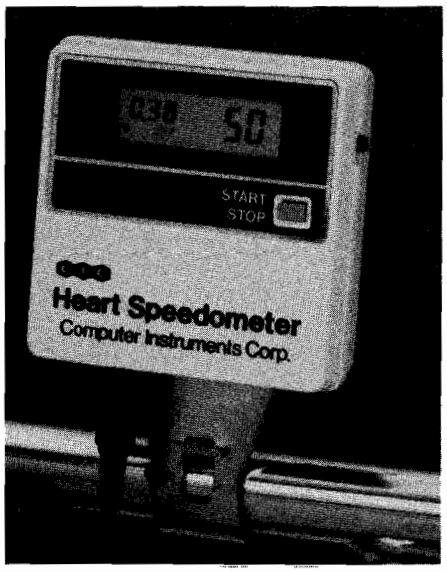


CIC Exersentry heart-rate monitor

EXHIBIT 6



CIC Heartwatch



CIC Heart Speedometer clip-on pulse meter

40 to 200 beats per minute. As long as you train within ten beats of your target heart-training zone (high or low), the unit will remain quiet. If you go beyond that range, the Exersentry will sound a warning beep.

Price: $180

The *Heartwatch 8799* and *8799S* monitor exercise and also give a monitor of heart rate and training target zones. They are capable of wireless transmission from the chest-strap ECG sensor to the wristwatch display, and will store the information for recall. They also function as full sports watches, with stopwatch, time functions, etc.

Price: under $400

CIC also has a series of clip-on pulse meters (models *8519* and *8629*) that can be attached to exercise cycles and rowing machines.

Price: from $120 to $160

Computer Instruments Corp.
100 Madison Ave.
Hempstead, NY 11550
800-227-1314

■

EXHIBIT 6

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Public Catalog

Copyright Catalog (1978 to present)
Search Request: Left Anchored Name = Goldman Bob
Search Results: Displaying 5 of 8 entries

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The "E" factor : the secrets of new tech training and fitness for the...

Type of Work: Text
Registration Number / Date: TX0002273392 / 1988-03-21
Title: The "E" factor : the secrets of new tech training and fitness for the winning edge / Bob Goldman and Ronald Klatz.
Edition: 1st ed.
Imprint: New York : W. Morrow, c1988.
Description: 575 p.
Copyright Claimant: Bob Goldman
Date of Creation: 1988
Date of Publication: 1988-03-11
Names: Klatz, Ronald
Goldman, Bob, 1955-

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EXHIBIT 6

LIBRARY OF CONGRESS CATALOG RECORD

The "E" factor : the secrets of new tech training and fitness for the ...

LC Control No.:	87021326
Type of Material:	Book (Print, Microform, Electronic, etc.)
Personal Name:	Goldman, Bob, 1955-
Main Title:	The "E" factor : the secrets of new tech training and fitness for the winning edge / Bob Goldman and Ronald Klatz.
Edition Information:	1st ed.
Published/Created:	New York : Morrow, 1988.
Related Names:	Klatz, Ronald, 1955-
Description:	xv, 575 p. : ill. ; 24 cm.
ISBN:	068806468X
Notes:	Bibliography: p. 515-557. Includes index.
Subjects:	Sports--Physiological aspects. Physical fitness. Sports medicine--Technological innovations.
LC Classification:	RC1235 .G65 1988
Dewey Class No.:	613.7/1 19

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/010,612 + 90/010366	07/17/2009	5,337,753	8185-82247-01	2033

7590 06/14/2010

EXAMINER	
ART UNIT	PAPER NUMBER

AXIL YALE & RISTAS LLP
750 Mail ST.
Suite 1400
HARTFORD, CT 06103-2721

DATE MAILED: 06/14/2010

Please find below and/or attached an Office communication concerning this application or proceeding.

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(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

Robert F. Scotti

Klarquist Sparkman, LLP

121 SW Salmon Street, Suite 1600

Portland, OR 97204

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/010,612*. 3 90/010366

PATENT NO. *5,337,753*.

ART UNIT *3992*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

PTOL-465 (Rev.07-04)

Notice of Intent to Issue Ex Parte Reexamination Certificate	Control No.	Patent Under Reexamination
	90/010,366 , 90/010612	5337753
	Examiner: ALEXANDER J. KOSOWSKI	Art Unit: 3992

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☒ Prosecution on the merits is (or remains) closed in this *ex parte* reexamination proceeding. This proceeding is subject to reopening at the initiative of the Office or upon petition. *Cf.* 37 CFR 1.313(a). A Certificate will be issued in view of
   - (a) ☒ Patent owner's communication(s) filed: *05 April 2010*.
   - (b) ☐ Patent owner's late response filed: _____.
   - (c) ☐ Patent owner's failure to file an appropriate response to the Office action mailed: _____.
   - (d) ☐ Patent owner's failure to timely file an Appeal Brief (37 CFR 41.31).
   - (e) ☐ Other: _____.

   Status of *Ex Parte* Reexamination:
   - (f) Change in the Specification: ☐ Yes ☒ No
   - (g) Change in the Drawing(s): ☐ Yes ☒ No
   - (h) Status of the Claim(s):
     - (1) Patent claim(s) confirmed: *1-16*.
     - (2) Patent claim(s) amended (including dependent on amended claim(s)): _____
     - (3) Patent claim(s) cancelled: _____.
     - (4) Newly presented claim(s) patentable: _____.
     - (5) Newly presented cancelled claims: _____.
2. ☒ Note the attached statement of reasons for patentability and/or confirmation. Any comments considered necessary by patent owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submission(s) should be labeled: "Comments On Statement of Reasons for Patentability and/or Confirmation."
3. ☐ Note attached NOTICE OF REFERENCES CITED (PTO-892).
4. ☐ Note attached LIST OF REFERENCES CITED (PTO/SB/08).
5. ☐ The drawing correction request filed on _____ is: ☐ approved ☐ disapproved.
6. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   - ☐ been received.
   - ☐ not been received.
   - ☐ been filed in Application No. _____.
   - ☐ been filed in reexamination Control No. _____.
   - ☐ been received by the International Bureau in PCT Application No. _____.

   * Certified copies not received: _____.
7. ☐ Note attached Examiner's Amendment.
8. ☐ Note attached Interview Summary (PTO-474).
9. ☐ Other: _____.

cc: Requester (if third party requester)

DETAILED ACTION

1) This Office action addresses claims 1-16 of United States Patent Number 5,337,753 (Lekhtman). Reexamination 90/010612 has been merged with reexamination 90/010366. This action is in response to the request for reconsideration filed 4/5/10. Claims 1-16 are now confirmed.

General Response

2) In response to the request for reconsideration filed 4/5/10, examiner notes the following:

The crucial claim language to be discussed is the following limitation of claim 1:

Whereby a first electromyogram signal will be detected between said first live electrode and said first common electrode, and a second electromyogram signal, of substantially equal magnitude and phase to said first electromyogram signal will be detected between said second live electrode and said second common electrode; so that, when said first electromyogram signal is applied to said first terminal and said second electromyogram signal is applied to said second terminal, the first and second electromyogram signals will be subtracted from each other to produce a substantially zero electromyogram signal at the output of said difference amplifier.

Effectively, this claim limitation requires that EMG signals (noise), which are detected through the same electrodes that detect ECG (heart rate) signals, be of substantially equal magnitude and phase so that they cancel each other out when fed through a difference amplifier.

In the most recent rejection of claim 1, examiner stated that the De Vel reference teaches that it was known to adjust the geometric properties of electrodes to help minimize noise, and that it would have been obvious to adjust the electrodes so that they create substantially equal EMG signals.

In the current response, patent owner (PO) argues that configuring the electrodes to substantially minimize the detected EMG from both hands on an exercise machine is not taught by the prior art, and that one of ordinary skill would adjust for noise downstream of the difference amplifier. PO also argues that De Vel discusses using bandpass filters downstream of the difference amplifier to increase S/N ratio, so there is no motivation to balance the EMG waveforms at the electrodes. PO also argues that the electrodes in De Vel were presumably placed close to the heart, rather than at a user's hands, which would result in a higher S/N ratio.

Examiner agrees that De Vel does not teach exactly how to adjust the geometric properties and locations of ECG electrodes to cancel out EMG using a difference amplifier. De Vel focuses on utilizing bandpass filters instead of balancing EMG from specific muscle groups, and appears directed towards heart rate measurements directly from the chest, rather than from electrodes gripped by a pair of hands. Therefore, the EMG waveforms as detected would not necessarily be of substantially equal magnitude and phase.

Therefore, in light of PO's arguments filed 4/5/10, as well as the declaration of Gregory Lekhtman filed 6/15/09, examiner withdraws the previous rejections. Examiner finds the presented arguments to be persuasive. Claims 1-16 are thereby confirmed as explained below.

A reasons for confirmation for claims 1-16 is below.

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

3) Claims 1-16 are confirmed.

The following is an examiner's statement of reasons for confirmation of the claims found patentable in this reexamination proceeding:

Referring to claim 1, the claim is confirmed over the prior art that was explained in the request and determined to raise a substantial new question of patentability in the order granting reexamination and over the prior art that was applied and discussed by the examiner in the present reexamination proceeding because that prior art does not explicitly teach a heart rate monitor for use by a user in association with an exercise apparatus and/or exercise procedures whereby a first electromyogram signal will be detected between said first live electrode and said first common electrode, and a second electromyogram signal, of substantially equal magnitude and phase to said first electromyogram signal will be detected between said second live electrode and said second common electrode; so that, when said first electromyogram signal is applied to said first terminal and said second electromyogram signal is applied to said second terminal, the first and second electromyogram signals will be subtracted from each other to produce a substantially zero electromyogram signal at the output of said difference amplifier, in combination with the remaining elements or features of the claimed invention.

Referring to claims 2-16, the claims are dependent on a confirmed independent claim, and are therefore also confirmed.

Conclusion

All correspondence relating to this ex parte reexamination proceeding should be directed as follows:

By U.S. Postal Service Mail to:

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Commissioner for Patents
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Registered users of EFS-Web may alternatively submit such correspondence via the electronic filing system EFS-Web, at

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Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

/Alexander J Kosowski/

Primary Examiner, Art Unit 3992

/CML/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
EX-PARTE REEXAMINATION

Control No.:	90/010,612 and 90/010,366 (Merged)
Patent No.:	5,337,753
Inventor:	Gregory Lekhtman
Title:	Heart Rate Monitor
TC/A.U.	3992
Examiner:	A. J. Kosowski
Docket No.:	8185-82247-01 and LEK/151/US

Mail Stop Ex Parte Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO OFFICE ACTION

Enclosed are:

Response to Office Action in Reexamination No. 90/010,612; and

Response to Office Action in Reexamination No. 90/010,366.

The Responses are identical except for the Control Number in the title.

Respectfully submitted,
GREGORY LEKHTMAN

By: _____
L. James Ristas
Registration No. 28,663
Alix, Yale & Ristas, LLP
Attorney for Applicant

Date: March 31, 2010
750 Main Street – Suite 1400
Hartford, CT 06103-2721
(860) 527-9211
Our Ref: LEK/151/US
LJR/io

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Date: March 31, 2010

_____
L. James Ristas, Reg. No. 28,663

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
EX-PARTE REEXAMINATION

Control No.:	90/010,612 and 90/010,366 (Merged)
Patent No.:	5,337,753
Inventor:	Gregory Lekhtman
Title:	Heart Rate Monitor
TC/A.U.	3992
Examiner:	A. J. Kosowski
Docket No.:	8185-82247-01 and LEK/151/US

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Alexandria, VA 22313-1450

Sir:

RESPONSE TO OFFICE ACTION IN REEXAMINATION
CONTROL NUMBER 90/010,612

In response to the Official Action in the merged proceedings, dated February 5, 2010, Patent Owner (Owner) requests reconsideration and allowance for the reasons set forth in the accompanying Remarks.

There are no Amendments to the Specification, Claims, Abstract or Drawing.

Remarks begin on page 2.

Mailing Certificate

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Date: March 31, 2010

L. James Ristas, Reg. No. 28,663

REMARKS

Claims 1-4 stand rejected under 35 U.S.C. §103(a) as unpatentable by the combination of the Fujisaki patent in view of the De Vel technical paper. Applicant respectfully traverses this grounds for rejection.

The examiner recognizes that Fujisaki does not teach the critical aspect of claim 1, that a first electromyogram signal (EMG) will be detected between the first live electrode and the first common electrode, and a second EMG signal, substantially equal in magnitude and phase to the first EMG signal, will be detected between the second live electrode and the second common electrode so that, when the first EMG signal is applied to the first terminal of the difference amplifier and the second EMG signal is applied to the second terminal of the difference amplifier the first and second EMG signals will be subtracted from each other to produce a substantially zero EMG signal at the output of the difference amplifier.

With the present invention, the EMG waveforms generated by the body and manifested differently in each hand, are nevertheless detected as substantially equal by the *a priori* selection of the electrode configuration. Thus, when the EMG signals from the electrodes are applied to opposite polarity terminals of a difference amplifier with equal amplitude and phase, the EMG signals are subtracted from each other to produce a zero level at the output of the difference amplifier.

Owner again emphasizes the important fact that ECG and EMG waveforms generated by a person are very different in how they are generated, where they are generated, how they travel through the body, their polarity, and the spatial dependence on their measurement. For monitoring heart rate from body surface sensors away from the heart, such as at hands on exercise equipment, ECG wave forms originate at the heart and travel a considerable distance to the hands, presenting an "R" wave amplitude of only about 100-1500 microvolts, along with AC noise and body hum in the microvolt range. The ECG

signal is masked by strong EMG signals on the hands during exercise on the machines, and the spectrum of the EMG signal is close to the spectrum of the "R" wave of the ECG signal. Conventional thinking based on ambulatory heart rate measurement was to pass the detected wave forms through a difference amplifier to reduce noise and then capture the important part of the amplified ECG signal with a band pass filter. Although Fujisaki appreciated that the purpose of the difference amplifier was to reduce noise while amplifying the ECG waveform, there is no indication in Fujisaki that he appreciated the special problems posed by the strong and unequal EMG waveforms relative to the weak but equal and opposite ECG waveform as manifested in the hands. Under these circumstances, the use of a difference amplifier and bandpass filer is inefficient, because the filtering degrades the quality of the ECG signal and reduces the signal to a noise ratio of ECG/EMG.

Thus, EMG wave forms were known before the claimed invention, to be a source of interference in the measurement of ECG. However, with an ECG sensor adjacent the heart as used in ambulatory heart rate monitoring, the ratio of ECG signal strength to EMG signal strength was high enough to more easily detect and count the "R" component of the ECG wave form. During exercise on machines, the EMG wave form on the palms of the hands increases 200-300 times from approximately 10 microvolts up to 2-5 millivolts, thereby overwhelming the ECG "R" wave amplitude of about 100-1500 microvolts with overlapping frequencies. EMG electrical potential is generated by muscle activity throughout the body but EMG potential on the skin is dominated by local muscle activity, and is not correlated with or commensurate to heartbeat

In Fujisaki, one electrode for each hand is active and the other is a common ground. With the device in use during exercise on a machine, the left active electrode would detect a faint ECG wave form traveling from the heart to the left palm, and a strong EMG wave form potential between the left active electrode and left ground. Similarly, the right active electrode would detect

substantially the same faint ECG wave form but of opposite polarity and a strong EMG wave form potential between the right active electrode and the right ground. Whereas the ECG wave forms on the left and right palms at the machine handle are substantially equal and of opposite polarity, the EMG wave forms are of the same polarity but different on the left and right palms. Although the purpose of the difference amplifier of Fujisaki is to cancel input signals that are of the same potential, magnitude and phase, while amplifying signals that are of opposite polarity, magnitude and phase, the EMG signals on the two active electrodes cannot be cancelled because they are not of the same magnitude and phase. Fujisaki does amplify the ECG signal but merely hopes to cancel noise in the difference amplifier. In actuality, even if some portions of the EMG wave forms from the left and right hands cancel each other, the substantially higher power of the EMG wave forms at the surface of the palms leaves a considerable residual EMG signal that is still high compared to the amplified ECG signal. Because the EMG wave forms manifested at the left and right hands are not equal, the fact that the two active electrodes of the Fujisaki patent provide the input to the difference amplifier and the two inactive electrodes are connected to a common potential does not overcome this inequality in EMG contribution, so the EMG contributions are neither equal nor cancelled.

Owner submits that neither Fujisaki nor any prior art of record teaches or suggests that the EMG signal as detected from the palms of a human grasping electrodes while exercising, could be attenuated or cancelled by a difference amplifier to the extent of substantially zero such that a reliable ECG to EMG signal to noise ratio could be used for isolating the "R" peaks and thereby counting the heart pulses. Only in the heart rate monitor disclosed in Owner's patent are the detected right EMG and detected left EMG signals close enough in magnitude and phase to effectively cancel out in the difference amplifier.

The De Vel paper adds nothing to Fujisaki that would resemble Owner's claimed invention. The examiner relies on De Vel for teaching that ECG signals, especially when measured for a user under physical stress, contain noise including EMG artifacts, that the level of this noise depends on the geometric properties and location of the surface electrodes, and that it is common to use a front-end difference input interface for detecting ECG signals and minimizing noise. Owner has already admitted as much, and believes that this fact strengthens, rather than weakens the claimed invention. Notwithstanding the known contamination of ECG signals by EMG signals, no one previously conceived the elegant solution of configuration the electrodes *a priori* to substantially equalize the detected EMG from both hands on an exercise machine, such that the difference amplifier would indeed subtract them and thereby significantly increase the ECG signal to noise ratio. There is no disclosure in Fujisaki that would indicate he recognized the severity of the problem caused by the disparity in EMG signals as he would conventionally detect them at the left and right hands.

Even if one speculates that Fujisaki was aware of the magnitude of the EMG masking the ECG at the hands, one must presume that Fujisaki believed either (1) the EMG signals were substantially equal on the left and right hands, so regardless of electrode size, a symmetric configuration would result in cancellation of the EMG by the difference amplifier, or (2) the EMG signals were not equal and thus would not be cancelled in the difference amplifier but would somehow be filtered out after the difference amplifier.

If one of ordinary skill were aware of the De Vel paper and considered it as a candidate for improving the Fujisaki monitor, the modification would be made to Fujisaki only downstream of the difference amplifier. However, since the De Vel paper discloses a technique for improving ambulatory heart rate monitoring during increases in body activity, the resulting combination of Fujisaki and De Vel would not necessarily improve Fujisaki. The wave forms shown in

Figure 1 of De Vel were presumably derived from electrodes placed close to the heart, so the ECG signal to noise ratio is much higher than would be measurable at the palms. Ambulatory heart monitoring is achieved using surface electrodes on the torso, i.e., near the heart, where the ECG waveform is much stronger than at the hands and therefore the EMG waveform does not present the masking problem to the extent present at the hands. The text beneath Fig. 2 and in the description at the bottom of the third column confirm that the De Vel technique is concerned only with the bandpass filter after the difference amplifier to increase the signal to noise ratio, so there is no concern whatsoever in balancing the detection of the EMG waveforms or signals at the surface electrodes that contact the skin.

The examiner asserts that De Vel teaches one to adjust the geometric properties and locations of the electrodes in order to minimize noise, and thus one would be motivated to configure the electrodes of Fujisaki so as to balance the detected EMG. This line of thinking cannot be derived form De Vel. De Vel does not disclose that he kept repositioning the ECG electrodes on the subject until he obtained a maximum ECG to EMG signal ratio. How would he know when such a maximum occurred, given that the EMG and ECG overlap? The most that one might infer from his paper is that because the EMG and ECG overlap and one cannot determine from signal strength alone when the electrodes are ideally positioned, he provides an improved bandpass filter technique downstream of the difference amplifier. Moreover, even if one were to find "ideal" positions for the ECG electrodes, there is no suggestion that the EMG waveforms <u>as detected</u> at those positions would be of equal magnitude and phase.

De Vel could not teach what the examiner has asserted, unless De Vel first measured only EMG on the torso during exercise (such as with BioSig's EMG monitor) and kept relocating and/or changing the electrodes until he obtained a "zero" EMG at the difference amplifier. Only after this *a priori* set up

based on EMG measurement alone, would he connect the heart rate monitoring circuit with ECG electrodes, difference amplifier, and bandpass filter in order to make heart rate measurements. This kind of EMG pre-balancing step (i.e., the present inventive concept) is not even hinted at in De Vel. Although he recognizes that the EMG signal is dependent on many variables, he simply does not teach how to adjust the geometric properties and locations of ambulatory ECG electrodes to cancel out EMG in the difference amplifier. There is no nexus between Fujisaki and De Vel by which the present inventive concept can be grafted onto Fujisaki.

De Vel discusses muscle noise spectrum associated with geometry and location of ambulatory ECG electrodes, and suggests that this noise is non-uniformly distributed. That is why he deals with it by designing a band pass filter. He never suggests balancing EMG from specific muscle groups. Even if De Vel thought about repositioning of the electrodes in order to obtain maximum ECG to EMG ratio, he would immediately realize that this could not be achieved by observing changes in the electrode signals as dependent on electrode locations and spacing. The electrode signals are a combination of overlapping ECG and EMG and the maximum of the ECG to EMG ratio cannot be determined without isolating one or the other, i.e., as by the *a priori* balancing of the EMG. He simply deals with body muscle artifacts as a noise and teaches how to eliminate this noise with a band pass filter.

Accordingly, even if prior to 1992, one of ordinary skill with knowledge of the Fujisaki patent recognized the possibility of improving the Fujisaki monitor by using the techniques described in De Vel, such person's attention would be focused on the filtering after the difference amplifier of Fujisaki, not on balancing the EMG signal from the electrodes *a priori* such that equal EMG magnitude and phase would be delivered to the difference amplifier.

At the time of Fujisaki and De Vel no one considered balancing the detected EMG signals from the muscles on the palms of the hands. Even

Owner's (Biosig's) prior techniques used a band pass filter after the difference amplifier. Fujisaki used a noise reduction filter after the difference amplifier, and De Vel used a band pass filter after the difference amplifier. Practitioners in the field at that time designed heart rate monitors for use during exercising based on techniques used in ambulatory heart rate monitoring, where the ECG generated by the heart alone was not overwhelmed by EMG generated by nearby muscle groups in the torso. For ambulatory monitoring, a difference amplifier and downstream filtering were somewhat satisfactory, but this technique was considerably degraded when ECG and EMG were detected in the hands. In the latter case, the ECG detected at the hands had traveled all the way from the heart and was very attenuated, whereas the EMG detected at the hands was from many muscle groups closer to the hands.

The present concept of balancing the detected EMG signal *a priori* at the electrodes elegantly and non-obviously solved a significant problem. The solution departed from standard thinking about using electrical components to amplify and filter contaminated ECG signals. By attacking the problem at the sensing electrode level rather than afterward, it permitted the use of a standard difference amplifier to achiever a stronger ECG to EMG signal to noise ratio, and use of filtering that focused on isolating the "R" peak of the ECG without interference from residual EMG that made it past the difference amplifier.

Owner refers to Mr. Lekhtman's Declaration Par. 48 and Exhibit 8 of the Owner's previously filed Response, regarding a contemporaneous technical paper comparing the accuracy of various heart rate monitors for exercise. These were primarily of the type having the sensor strapped to the heart. The author concluded that these were surprisingly inaccurate, and suspected that even with the sensors close to the heart, other locally manifested electrical activity (such as EMG) was the cause. This inaccuracy would be even greater for handle monitors (See Declaration Par. 53-54). That Owner solved this more difficult problem in striking fashion, is confirmed by the commercial success of the present invention,

both in terms of the company's consulting and sales, licensing of third parties, and unauthorized copying (infringement) by Nautilus (the Requester) and others. (See Declaration Par. 11, 55, 70, and 96-99).

Claim 2 stands or falls with claim 1.

Claim 3 recites additionally patentable subject matter because no one previously recognized the ideal form of the electrodes as rings, for balancing detected EMG during exercise while also detecting ECG. Fujisaki's electrodes are rod shaped cylinders, each having a wide area that is not conducive to being uniformly grasped during exercise. With this configuration, the surface areas of contact between the hand and each detector will vary from person to person and for a given person will vary as the position of the hands changes during heavy exercise. The EMG waveform detected at the left and right hands cannot be substantially equal. In addition, as set forth in Declaration Par. 43, the large surface area of the electrodes as illustrated in Fujisaki confirms that Fujisaki was not aware of the principles of EMG detection relied on by the present inventor to make the invention claimed in the '753 patent. In particular, the use of large electrodes has the doubly detrimental effects of (a) magnifying the strength of the detected EMG relative to the detected ECG, thus reducing the ECG/EMG signal to noise ratio and (b) increasing the inequality and time dependent variance between left and right hand EMG resulting from continual changes in contact area between the hands and the electrodes during exercise. In contrast, the claimed ring detector electrodes are relatively narrow and spaced apart, and are very likely to be completely covered by (in contact over the entire detector area with) the hands throughout an exercise routine, regardless of shifting hand position on the handle.

Although the Biosig and E-Factor monitors utilized ring electrodes, neither of these has a left live ring and a left common ring, and a right live ring and a right common ring. When EMG is balanced *a priori*, the present claimed configuration simultaneously implements a four electrode EMG system and a

three electrode ECG system. As set forth in Declaration Par. 71, the EMG signals at the hands, in association with exercise, can only be cancelled in a difference amplifier, if the detectors are balanced *a priori*. Such balancing requires four EMG electrodes vs. three ECG electrodes. In relationship to a heart four electrodes represent three electrodes, because two common electrodes are connected. In relationship to EMG generators of the palms of the hands there are four electrodes, because each pair of electrodes measures the difference of potentials on each palm of the hand. If these potentials are not balanced, the result will be an amplified EMG signal. If the electrodes are balanced, the result will be cancellation of EMG signals.

None of the prior art suggests the combination of ring electrodes according to the recitation of claim 3, with the features recited in claim 1.

With respect to claim 4, applicant's band pass filer is directly connected to the difference amplifier, for the purpose of extracting the "R" portion of the amplified and isolated ECG waveform. Instead, Fujisaki provides a "noise filter" after the difference amplifier, without specifying how this filter operates. One must presume that this is intended to "filter out" unwanted waveforms, not isolate the "R" peak. Although these extraneous waveforms include EMG, Fujisaki does not specifically recognize EMG as requiring special treatment, and certainly does not even hint at balancing the EMG in any manner, let alone at the electrode detectors where grasped by the hands, i.e., at a point upstream of the difference amplifier.

The previous Biosig Insta-Pulse monitors utilized a band pass filter directly connected to the difference amplifier to isolate the "R" wave, but suffered from degradation during exercise due to the passing of contaminating EMG waveforms through the difference amplifier. Fujisaki would not have incorporated features of the prior art Biosig monitors into his circuit (i.e., directly connecting a band pass filter to his unspecified "noise filter" between his difference amplifier and the pulse generating circuit) because that is the location of his noise filter.

The previous Biosig monitors also employed a threshold to generate a square pulse to be counted.

However, none of the prior art suggests the combination of signal processing immediately following the difference amplifier per claim 4, the ring electrodes according to the recitation of claim 3, and the features recited in claim 1.

Dependent claims 5-8 and 10-16 were rejected under 35 U.S.C. §103 on the basis of the combined disclosures of Fujisaki, De Vel, "Biosig" and "E-Factor".

Claims 5, 6, 7, 8 and 10 stand or fall with claim 4.

Claims 11 and 12 stand or fall with claim 1.

Claim 13 is patentable for the same reasons as argued for claim 3.

Claim 14 is patentable for the same reasons as argued for claim 14.

Claims 15 and 16 stand or fall with claim 14.

Although the Hawkins patent cited by the Requester was not relied on to reject any claims, Owner notes that the equipment described in Hawkins does not monitor heart rate during exercise (see col. 7 lines 4-44) and in any event uses only two electrodes. It is designed to evaluate the heart recovery rate after exercise. The user does not even touch the electrodes during exercise, only before and after. Furthermore, although rings are shown, there is no disclosure as to whether the left pair are active and common, and the right pair are active and common. In fact, the description refers to only two electrodes, 38 and 40, which generate two signals (see col. 4 lines 12-20). Finally, there is no recognition or discussion of handling noise, especially EMG, presumably because EMG is far less of a problem when the user simply holds the handles after exercising. No one in the art would find anything in Hawkins to modify Fujisaki.

For the foregoing reasons, applicant believes that all pending claims are patentable.

Respectfully submitted,

GREGORY LEKHTMAN

By: _____

L. James Ristas
Registration No. 28,663
Alix, Yale & Ristas, LLP
Attorney for Applicant

Date: March 31, 2010
750 Main Street – Suite 1400
Hartford, CT 06103-2721
(860) 527-9211
Our Ref: LEK/151/US
LJR/io

CERTIFICATE OF SERVICE

I hereby certify that on this 31st day of March, 2010, a true and correct copy of the foregoing Response to Office Action in Reexamination Control Number 90/010,612 was mailed, first-class postage paid, to the attorney of record for the Requester:

Robert F. Scotti
KLARQUIST SPARKMAN, LLP
One World Trade Center, Suite 1600
121 S.W. Salmon Street
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/010,612 + 90/010366	07/17/2009	5,337,753	8185-82247-01	2033

7590 02/05/2010

AXIL YALE & RISTAS LLP
750 Mail ST.
Suite 1400
HARTFORD, CT 06103-2721

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 02/05/2010

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

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(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

Robert F. Scotti

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EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/010,612*. 3 90/010366

PATENT NO. *5,337,753*.

ART UNIT *3992*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Office Action in Ex Parte Reexamination	Control No. 90/010,612 (90/010,366)	Patent Under Reexamination 5,337,753	
	Examiner ALEXANDER J. KOSOWSKI	Art Unit 3992	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

a☒ Responsive to the communication(s) filed on *6/15/09,7/17/09* . b☐ This action is made FINAL.
c☐ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire *2* month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Information Disclosure Statement, PTO/SB/08.
3. ☐ Interview Summary, PTO-474.
4. ☐ ____.

Part II SUMMARY OF ACTION

1a. ☒ Claims *1-16* are subject to reexamination.
1b. ☐ Claims ___ are not subject to reexamination.
2. ☐ Claims ___ hav e been canceled in the present reexamination proceeding.
3. ☒ Claims *9* are patentable and/or confirmed.
4. ☒ Claims *1-8 and 10-16* are rejected.
5. ☐ Claims ___ are objected to.
6. ☐ The drawings, filed on ___ are acceptable.
7. ☐ The proposed drawing correction, filed on ___ has been (7a) ☐ approved (7b)☐ disapproved.
8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   1☐ been received.
   2☐ not been received.
   3☐ been filed in Application No. ____.
   4☐ been filed in reexamination Control No. ____.
   5☐ been received by the International Bureau in PCT application No. ____.
   * See the attached detailed Office action for a list of the certified copies not received.
9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.
10. ☐ Other: _____

cc: Requester (if third party requester)

DETAILED ACTION

1) This Office action addresses claims 1-16 of United States Patent Number 5,337,753 (Lekhtman). Reexamination 90/010612 has been merged with reexamination 90/010366 in the Decision Merging Proceedings mailed 12/14/09. With regard to 90/010366, a response was filed on 6/15/09 in response to the non final office action mailed 4/13/09. With regard to 90/010612, an Order granting reexamination was mailed 9/30/09 in response to the second reexamination request filed 7/17/09. This is a second non-final rejection addressing the merged proceedings in light of the new prior art submitted in the second request for reexamination.

References Utilized

U.S. Pat 4,444,200 (Fujisaki)

De Vel (R-Wave Detection in the Presence of Muscle Artifacts)

Trademark Specimen, Reg. No. 1,156,243 (Biosig)

The "E" Factor Book (E-Factor)

Claim Rejections - 35 USC § 103

2) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3) Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable by Fujisaki et al (U.S. Pat 4,444,200), further in view of De Vel (R-Wave Detection…)

Referring to claim 1, Fujisaki teaches a heart rate monitor for use by a user in association with exercise apparatus and/or exercise procedures, comprising;

an elongate member (Fujisaki, Figure 1);

electronic circuitry including a difference amplifier having a first input terminal of a first polarity and a second input terminal of a second polarity opposite to said first polarity (Fujisaki, col. 3 lines 3-10 and Figure 3, whereby a differential amplifier is utilized);

said elongate member comprising a first half and a second half (Fujisaki, Figure 1);

a first live electrode and a first common electrode mounted on said first half in spaced relationship with each other and a second live electrode and a second common electrode mounted on said second half in spaced relationship with each other (Fujisaki, col. 2 lines 43-63 and col. 3 lines 3-10 and Figures 2-3, whereby left and right hand grips and inner and outer electrodes are used);

said first and second common electrodes being connected to each other and to a point of common potential (Fujisaki, col. 3 lines 10-13 and Figure 1, whereby ground is considered the point of common potential);

said first live electrode being connected to said first terminal of said difference amplifier and said second live electrode being connected to said second terminal of said difference amplifier (Fujisaki, col. 3 lines 3-10 and Figures 1 and 3, whereby live electrode connections are attached to inputs of the differential amplifier);

a display device disposed on said elongate member (Fujisaki, Figure 1, #12);

wherein, said elongate member is held by said user with one hand of the user on said first half contacting said first live electrode and said first common electrode, and with the other hand

of the user on said second half contacting said second live electrode and said second common electrode (Fujisaki, col. 4 lines 46-48, whereby grip sensors are used with two contacts each);

and whereby a first electrocardiograph signal will be detected between said first live electrode and said first common electrode and a second electrocardiograph signal, of substantially equal magnitude but of opposite phase to said first electrocardiograph signal will be detected between said second live electrode and said second common electrode; so that, when said first electrocardiograph signal is applied to said first terminal and said second electrocardiograph signal is applied to said second terminal, the first and second electrocardiograph signals will be added to each other to produce a non-zero electrocardiograph signal at the output of said difference amplifier (Fujisaki, col. 3 lines 13-26, col. 4 lines 40-61 and Figure 3, whereby the circuit configuration taught by Fujisaki utilizing a differential amplifier circuit results in an output which would add both input signals, and whereby Fujisaki teaches two live and two common electrodes to be gripped by opposite hands for measuring pulse rate signals, whereby examiner notes that heart signals in each hand are known to be of opposite phase);

means for measuring time intervals between heart pulses on detected electrocardiograph signal (Fujisaki, col. 3 lines 3-26 and Figure 3, whereby a filter and pulse generator are utilized to create output pulses on every heart beat to measure time intervals);

means for calculating the heart rate of said user using said measure time intervals (Fujisaki, col. 3 lines 28-38, whereby a microprocessor calculates heart rate);

said means for calculating being connected to said display device, whereby, the heart rate of said user is displayed on said display device (Fujisaki, Figure 3 and col. 4 lines 52-59, whereby a display is coupled to the microprocessor).

In addition, Fujisaki teaches that "AC hum and human body hum" (referred to as "noise") will also be detected by the electrodes (col. 3 lines 1-2). The circuit diagram of Fujisaki also shows that any of this detected noise will be fed into the differential amplifier circuit. However, Fujisaki does not explicitly teach whereby a first electromyogram signal will be detected between said first live electrode and said first common electrode, and a second electromyogram signal, of substantially equal magnitude and phase to said first electromyogram signal will be detected between said second live electrode and said second common electrode so that, when said first electromyogram signal is applied to said first terminal and said second electromyogram signal is applied to said second terminal, the first and second electromyogram signals will be subtracted from each other to produce a substantially zero electromyogram signal at the output of said difference amplifier.

De Vel teaches on pages 715-717 that ECG signals, especially when measured for a user under physical stress, contain noise including EMG artifacts. De Vel also teaches that the level of this noise depends on the geometric properties and location of the surface electrodes, and that it is common to use a front-end differential input interface for detecting ECG signals and minimizing noise. The differential amplifier circuit of Fujisaki would therefore have an input including EMG noise as well as ECG signals, and would therefore subtract the EMG signals from both inputs, with the ability to adjust EMG magnitude and phase based on electrode positioning.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to adjust the electrodes in the invention taught by Fujisaki so as to create substantially equal EMG signals which would therefore create substantially zero EMG signals at the output of a difference amplifier since it is desirable to reduce extraneous noise components when measuring ECG signals (De Vel, Page 715, Introduction), and since it was known that careful selection of optimum surface electrode geometry can eliminate false positive readings by reducing noise (De Vel, Pages 716-716, Discussion). In addition, both Fujisaki and De Vel are analogous art because both disclose techniques for reducing noise in heart rate measurement.

Referring to claim 2, Fujisaki teaches wherein said elongate member comprises a hollow cylindrical member, said electronic circuitry being housed in the interior of said hollow cylindrical member (Figure 1, whereby a center casing with cylindrical members houses the electronic circuitry).

Referring to claim 3, Fujisaki teaches wherein said first live electrode comprises a first ring member of a conductive material mounted on said first half of said elongate member, and wherein said first common electrode comprises a second ring member of a conductive material mounted on said first half of said elongate member and spaced from said first ring member, and wherein said second live electrode comprises a third ring member of a conductive material mounted on said second half of said elongate member and wherein said second common electrode comprises a fourth ring member of a conductive material mounted on said second half

of said elongate member and spaced from said third ring member (Figures 1 and 2, whereby there are four ring members that form the electrodes, and spacers separate the live electrodes).

Referring to claim 4, Fujisaki teaches wherein said means for measuring time intervals comprises a bandpass filter, the output of said difference amplifier being connected to an input of said bandpass filter; and wherein said means for calculating the heart rate comprises; a microprocessor, the output of circuit elements being connected to an input of said microprocessor; the output of said microprocessor being connected to said display device (Figure 3 and col. 3 lines 3-26 and col. 4 lines 52-59, whereby a filter is connected to outputs of the differential amplifier and input into the microprocessor, and whereby time intervals of pulses are measured and utilized to computer and display the heart rate). However, Fujisaki teaches that the output of the filter is sent to a pulse generator, and not specifically a threshold limiter.

Examiner notes that the threshold limiter as claimed is defined in the specification as being utilized to produce square pulses to be send to the microprocessor. The pulse generator taught by Fujisaki is also utilized to generate rectangular pulse signals. Therefore, both elements are functionally equivalent.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to utilize a pulse generator as taught by Fujisaki as a type of threshold limiter in the invention taught above since these would both produce square waves from the output of a bandpass filter, and since threshold limiters are well known in the art.

4) Claims 5-8, 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujisaki, further in view of De Vel, further in view of Biosig and E-Factor.

Referring to claims 5-8, 10-12, Fujisaki and De Vel teach the above, However, they do not explicitly teach that said display device comprises a pulse indicator adapted to be illuminated each time a heart pulse of the user is detected, that elasticized plugs force-fit into both ends of said cylindrical member, whereby, the interior of said hollow cylindrical member is waterproofingly sealed, including a stand means for mounting the monitor on the floor; said stand means including a base and an upwardly extending member, including a means for mounting said monitor on a wall; said means comprising a base, wherein said cylindrical member is mounted on an exercise apparatus, wherein said elongate member is mounted on an exercise apparatus, and wherein said electronic circuitry being mounted in said exercise apparatus, wherein said elongate member comprises a hollow cylindrical member.

Biosig teaches a 3 digit numerical indication of pulse rate along with a red dot that illuminates during a user's pulse (Exhibit 5), E-Factor teaches a watertight enclosure (Page 245), Biosig teaches plugs in the end of an elongate member (Exhibit 5, whereby examiner takes official notice that elasticized materials are well known in the art), E-Factor teaches a stand means and wall bracket with base (Pages 244-245), E-Factor teaches the use of pulse meters while exercising and teaches that pulse meters can be mounted and integrated into exercise bikes (Pages 244-247), and Biosig teaches that the elongate member comprises a hollow cylindrical member.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to utilize the limitations above in the invention taught by Fujisaki and De Vel since

heart-rate monitors are well known as a guide in exercise, and provide personal motivation, preventative diagnostic tools, and biofeedback instruments all in one (E-Factor, page 244), since E-Factor discusses Biosig products specifically, and since examiner notes indication of pulse would provide multiple types of visual feedback for users during exercise.

Referring to claim 13, Fujisaki teaches that said first live electrode comprises a first ring member of a conductive material mounted on said first half of said elongate member, and wherein said first common electrode comprises a second ring member of a conductive material mounted on said first half of said elongate member and spaced from said first ring member; and wherein said second live electrode comprises a third ring member of a conductive material mounted on said second half of said elongate member and wherein said second common electrode comprises a fourth ring member of a conductive material mounted on said second half of said elongate member and spaced from said third ring member (Figures 1-2 and col. 2 lines 43-48, whereby four rings are cylindrical conductive electrodes with spacers).

Referring to claim 14, see rejection of claim 4 above.

Referring to claim 15, see rejection of claim 5 above.

Referring to claim 16, see rejection of claim 6 above.

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

5) Claim 9 is confirmed.

The following is an examiner's statement of reasons for patentability and/or confirmation of the claim found patentable in this reexamination proceeding:

The prior art of record, alone or in combination, does not explicitly teach a heart rate monitor including insert means, said insert means comprising a paper-like material having graphics and alphabetic information imprinted on one surface thereof; said hollow cylindrical member comprising a transparent material; said insert means being inserted into said hollow cylindrical member such that the graphics are disposed against the wall of said hollow cylindrical member so that said graphics can be seen on the outside of said hollow cylindrical member, in combination with the remaining elements or features of the claimed invention.

Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation" and will be placed in the reexamination file.

Response to Arguments

6) To begin, examiner notes that although not all the prior art specifically proposed by requester in the requests filed 7/17/09 and 12/19/08 have been utilized in the rejection above, patent owner is reminded that all proposed prior art that has raised an SNQ must be overcome before issuance of a reexamination certificate.

Patent owner's (PO's) response filed 6/15/09 has effectively been rendered moot in view of the second non-final office action above. However, examiner will still address some of the key arguments in view of requester's newly cited prior art.

First, examiner will again note confirmation of claim 9 as stated above. Although requester has pointed out that the submitted trademark specimen appears to read on this claim, it

is not clear to the examiner from the trademark filing exactly what materials are used, nor that the design submitted was actually the insert used for the device.

Next, examiner notes that PO's entire response filed 6/15/09 has been given due consideration, including the declaration of Gregory Lekhtman.

PO's main arguments were that 1) Fujisaki does not teach EMG and does not teach adapting or tuning to cancel EMG signals using a differential amplifier, and that 2) the electrode configuration of Fujisaki would not be effective to reduce EMG.

With regard to argument #1 above, examiner notes the modified rejection above. De Vel teaches that EMG exists as part of body noise when measuring ECG, and that it is common to use a front-end differential input interface for detecting ECG signals and minimizing noise.

With regard to argument #2 above, examiner again notes the modified rejection above. De Vel teaches that the level of noise depends on the geometric properties and location of the surface electrodes, and that it was known to adjust these properties in order to help minimize noise.

Therefore, the combination of Fujisaki with De Vel reads on the claimed invention, and one skilled in the art would have been motivated to combine the references for the reasons given above.

Most of PO's and declarant's remaining arguments have been rendered moot as they are directed towards only Fujisaki and not towards Fujisaki as modified by De Vel above. In addition, the rejection of claims 2-8 and 10-16 have been maintained from the previous rejection and were not specifically argued in PO's response filed 6/15/09.

Conclusion

All correspondence relating to this ex parte reexamination proceeding should be directed as follows:

By U.S. Postal Service Mail to:

Mail Stop Ex Parte Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX to:

(571) 273-9900
Central Reexamination Unit

By hand to:

Customer Service Window
Randolph Building
401 Dulany St.
Alexandria, VA 22314

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EFS-Web offers the benefit of quick submission to the particular area of the Office that needs to act on the correspondence. Also, EFS-Web submissions are "soft scanned" (i.e., electronically uploaded) directly into the official file for the reexamination proceeding, which offers parties the opportunity to review the content of their submissions after the "soft scanning" process is complete.

14) Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

/Alexander J Kosowski/

Primary Examiner, Art Unit 3992

ESK

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BIOSIG INSTRUMENTS, INC., Plaintiff, v. THE NAUTILUS GROUP, INC., Defendant.	Case No. 04 CIV. 6654 (AKH)

EXPERT REPORT OF HENRIETTA GALIANA, Ph.D

I, Henrietta Galiana, Ph.D, have been retained by counsel for Biosig Instruments, Inc. to act as an expert witness in this lawsuit. I expect to testify regarding the matters and opinions stated in this report, if asked about these matters and opinions by the Court or by the parties' attorneys.

I. SUMMARY

1. I am the chairman of the Department of Biomedical Engineering at McGill University, and have served on the University faculty since 1984, after receiving a Ph.D in Electrical Engineering (focused in Biomedical Engineering.) I have spent most of my career studying biosignal acquisition and processing, working primarily with non-invasive surface electrodes. Surface electrodes are conductive materials that when placed on the skin of a subject, can be used to detect muscle activity (EMG), eye movements (EOG), brain activity (EEG), or electrical heart signals (ECG or EKG). Over the course of my career, I have measured and analyzed these types of signals in many different contexts-- as a researcher, in a peer review capacity, as a participant and organizer of conferences, and as a supervisor of post graduate theses research and post doctoral fellows.

2. As part of my work on this matter, I studied U.S. Patent No. 5,337,753 (the '753 patent; Exhibit 1), the records of the communications with the Patent Office during the patenting process, the report of Dr. Joseph Dyro relating to the '753 patent, among the other documents and things referred to in this Report.

3. I believe that the '753 patent describes the patent's invention in a manner enabling a person of ordinary skill in the art to readily make the invention. Indeed, I handed the patent's Figure 1 and 2 alone (schematic circuit diagram) to one of my research assistants, and within two hours he built a working model of the very aspects of the invention that Dr. Dyro's report alleges to be unworkable.

4. The '753 patent describes an operative invention. Following the direction of the patent, my research assistant readily built a working model of the invention which substantially reduces to zero biosignals (EMG) emitted by the two hands of a subject and noise from external interference, while amplifying electrical signals (ECG) emitted by the subject's heart.

5. I studied the expert report of Dr. Dyro and considered his deposition testimony, and disagree with his theoretical conclusion that the '753 patent describes neither an operative invention, let alone one that could be made by a person of ordinary skill in the art from a reading of the patent. My testing of a working model of the invention built by my research assistant, establishes that the invention is in fact operative, and that the patent's description is sufficiently detailed to permit the invention to be reconstructed in a reasonable time by a person of ordinary skill in the art, and without the need for any significant experimentation.

6. Dr. Dyro's theoretical conclusions appear to me to be based on unsupported assumptions. For example, he states that EMG emitted from two hands of a subject will be amplified, not reduced by a differential amplifier. I attach data to this report demonstrating exactly the opposite occurs when following the instructions in the patent. That is, my testing demonstrates *that with the circuit connections in the patent,* the EMG from both hands and from electrical power noise are both reduced to substantially zero by the differential amplifier.

7. While an individual muscle fiber's electrical signal might be random, a skin contact sensor such as described in the '753 patent, can aggregate a multitude of electrical signals emitted by the muscle fibers that lie beneath the skin in the vicinity of the contact sensor. In addition, the contact sensor will react differently depending on its interconnections with an electronic circuit. As my test results demonstrate, the aggregate EMG signal detected by each of the surface electrodes on a subject's hands must be substantially the same in both amplitude and

phase, in part due to the fact that the invention connects both hands to the same point of common potential and uses closely spaced electrodes under each hand. As a result, the EMG signals from two hands become substantially correlated and can be eliminated by a differential amplifier, just as the '753 patent describes. In other words, my testing demonstrates that the invention works precisely as the '753 patent explains, and that the `753 patent contains a written description of the invention and the manner of making it to a clear level of detail sufficient to have enabled a person of ordinary skill in the art in 1992 to make the invention without any material experimentation required.

II. EDUCATION AND EXPERIENCE

8. I have been involved in the fields of electrical and biomedical engineering since 1961, when I began studying electrical engineering at McGill University in Montreal, Canada. In 1966, I received an undergraduate degree in Electrical Engineering, (Honors Stream), from McGill, and thereafter spent two years as a biomedical engineering research assistant in McGill's Electrical Engineering Department, and three years as a research staff engineer at the Massachusetts Institute of Technology (M.I.T). After taking time off to raise a family, I returned to McGill in 1977 as a doctoral student in Biomedical Engineering. I received a Ph.D in Biomedical Engineering from McGill in 1981, and spent the next three years as a Post-Doctoral Fellow at McGill's Aerospace Medical Unit in the Department of Physiology. In 1984, I became an Assistant Professor in the Department of Biomedical Engineering, and the next year was given Associate Memberships in McGill's Departments of Electrical Engineering and Otolaryngology (OTL). I was promoted to full professor in 1994, and in 2007 was appointed Chair of the Biomedical Engineering Department.

9. My accomplishments in the field of biomedical engineering were recognized by the Institute of Electrical an Electronics Engineers (IEEE) when it conferred upon me the status

of IEEE Fellow in 2002, which according to IEEE standards is conferred by the Board of Directors in recognition of "unusual distinction in the profession" and "an extraordinary record of accomplishments." (Appendix 2) In any given year, the distinction of Fellow is conferred upon no more than one tenth of one percent of the membership.

10. A major area of my expertise is in biosignal acquisition and processing. (understanding how the human body generates and transmits electrical signals, and how to detect, process and record those signals). My curriculum vitae is attached as Appendix 3 to this Declaration. I believe that I have considerable experience that is directly pertinent to the issue of how the '753 patent processes electrocardiograph (ECG) and electromyogram (EMG) signals and an appreciation of how the invention of the '753 patent works.

11. In the course of my undergraduate and graduate training, I studied courses in electrical engineering, mechanical engineering, electrophysiology, physiology, circuit theory and analysis, physics, statistics, and signal processing.

12. I was involved in designing and I teach graduate level courses in bioinstrumentation, biomedical engineering, and modeling and identification of biomedical systems. These courses involve detection, measurement, and processing of biosignals, including ECG and EMG, among others.

13. In the course of graduate level research supervision, I routinely guide the design of test protocols for biosignal data acquisition, for calibrating the devices involved, and for evaluating the resulting data. For example, I am involved in supervising graduate work involving fetal monitoring of ECG during childbirth. This requires the extraction of a small fetal ECG against the background of the mother's muscle noise during contractions and the mother's ECG. I have also become involved in projects outside the University. Also, in collaboration with

The Montreal Children's Hospital, I am currently involved in investigating methods to process noisy signals from neonatal respiration monitors, to robustly identify episodes of potentially deadly apnea. We have already developed robust automated algorithms to detect the presence of apnea in the presence of movement artifacts (EMG noise), and to provide an early warning to the nursing staff. I have presented lectures worldwide and published scientific articles that involve the processing and interpretation of various types of biosignals for the better understanding of processes in physiological systems, leading to relevant bio-system models and their application to clinical screening.

14. Throughout my career, I have regularly used differential amplifiers to process and record bio-signals, to eliminate unwanted signals and enhance signals of interest. I am very familiar with the use of differential amplifiers.

15. This is the first time that I have been retained to serve as an expert in any legal proceeding.

16. I am a past president of the IEEE Engineering in Medicine & Biology Society, (EMBS) and this year received EMBS's 2008 Career Service Award. I am also the Associate Editor of IEEE Transactions on Neural Systems and Rehabilitation Engineering (TNSRE) and an *ad hoc* reviewer for multiple neuroscience and movement control journals.

17. I am a Fellow of the Engineering Institute of Canada, and I serve on grant review committees for the Natural Sciences and Engineering Research Counsel (NSERC, Canada) and the Canadian Institutes for Health Research (CIHR), and served on the U.S.'s National Science Foundation's review Panel for Collaborative Research in Computational Neuroscience (2008).

A. INFORMATION CONSIDERED

18. The documents that I reviewed and rely upon are cited in this report. In forming the opinions that are expressed in this report, I have relied on the information in these documents, those provided by Dr. Dyro, as well as my own general knowledge. At trial, I may also present demonstrative exhibits to illustrate my testimony. I have attached as Appendix 4 a more comprehensive list of documents I considered or reviewed in the preparation of this report.

B. THE LEVEL OF ORDINARY SKILL IN THE ART

19. For purposes of this analysis, I accept Dr. Dyro's statement of a person of ordinary skill in the art in 1992, assuming that person had a minimum competence in the nature of biosignals and their acquisition.

C. OPINIONS TO BE EXPRESSED AND THE BASES AND REASONS THEREFORE

20. I have studied the expert report of Dr. Dyro, and believe that his conclusions about lack of operability of the '753 invention, lack of enablement, and lack of written description are incorrect.

21. There can be no doubt that the '753 patent describes an operative invention. Dr. Dyro's opposite conclusion is based on the incorrect premise that EMG signals detected by surface electrodes on opposite hands of a subject can not be substantially equal to each other in phase and amplitude, and as a result will be amplified rather than reduced by a differential amplifier. While Dr. Dyro expresses a theory, I have directly tested the circuit described in the '753 patent and demonstrate in data included in this report (as discussed later in greater detail) that two *detected* EMG signals on opposite hands can indeed have substantially the same amplitude and phase, and that a difference amplifier will then reduce those EMG signals to

substantially zero. This result is attributed to the interconnection of four electrodes (two for each hand) with a differential amplifier as described in the '753 patent.

III. BACKGROUND

A. Basic Principles of Differential or Difference Amplifiers

22. In referring to the components of signals used as inputs of differential amplifiers, the term "in-phase" is often used to describe whether the amplitude of two signals is the same (or nearly-so), while synchronized in their zero-crossings. This term is indeed relevant in describing the timing of peaks and troughs between pure sinusoidal signals. For more complex signals (such as ECG and EMG), the term "in-phase" is accepted in the art as referring to two signals that have a synchrony in the times of their zero-crossings with amplitudes of the *same* polarity. "Out-of-phase" describes two signals with synchronized zero crossings but *opposite* polarity. This more general definition is accepted by persons of ordinary skill in the art to characterize or quantify similarities/dissimilarities in either pairs of sine waves, or pairs of more complex noisy signals (*e.g.*, ECGs and EMGs) (Appendix 5).

23. Consider two signals applied to the signal input ports of a difference amplifier:

Signal1 = m1 + n Signal2= m2 + n

where *n* represents noise common to both signals and where m1 is the opposite of m2 (m1= -m2) Because m1 and m2 are equal and of opposite signs, they both reach zero amplitude at the same time (timings of their zero crossings are the same) but they do so moving in opposite directions. As a result the signal pair is referred to as being *out of phase*. By definition, a differential amplifier is designed to amplify the difference (by a factor A) and reduce the sum of the inputs by a factor B, much smaller than A. In other words, the difference between m1 and m2 will be greatly amplified by a factor A.

24. On the other hand, the common signal *n* will not be amplified and instead pass through the amplifier with a gain B much smaller than A (usually B= 1). In order to further eliminate noise 'n', that noise must also be carried on a reference electrode connected to what is referred to as a "common reference port" on the differential amplifier. Using the common reference signal, the differential amplifier compares the input signals to the reference signal, and substantially rejects the noise component to the extent they are common. Because differential amplifiers process signals based on the instantaneous amplitude (reflecting the polarity, timing of zero crossing, and magnitude), and not necessarily the more limited characteristics of a sine wave, it is improper in the context of differential amplifiers, to limit the definition of phase to that used in sine waves. Rather, a more general definition of phase and magnitude (as referred to in ¶ 22 above) is commonly understood by persons of ordinary skill in the art to apply to the operation of differential amplifiers.

25. While it is common to speak of the "rejection" or "elimination" of noise by a differential amplifier, persons of ordinary skill in the art understand that complete elimination is never achievable due to physical limits in electronic components. Shared noise (i.e., common mode) will always 'leak' through on the output of any differential amplifier, and this is characterized by what is referred to in the art as the common-mode-rejection-ratio (CMRR) Appendix 6.

26. The CMRR is defined as the ratio of the difference gain over the sum gain, (or A/B above). Typical bio-applications require a CMRR of 10,000-100,000; while the common mode is typically of gain 1. With such high CMRR, one can see why *one skilled-in-the-art refers to a 'substantially zero' response to common signals* on the two terminals, simply because it is substantially smaller than the response to opposite signals on the two terminals. This does

not and is never expected to mean that the noise component will be attenuated to perfect zero by the differential amplifier.

27. As a result, amplification of desired signals, and relative attenuation (rejection) of undesired signals is dependent on appropriate selection of recording sites and circuit connections. Desired signal components should appear with opposite polarity on the two differential amplifier input ports, while noise (*i.e.*, undesired signals) should appear of substantially equal magnitude (amplitude) and phase on the same two input ports, *and on the common reference port.* The location of the *reference* electrode and its connection to the amplifier circuit will therefore also influence the nature of common signals on the two input signals amenable to cancellation.

28. Dr. Dyro provides one example in his report (Dyro report, Figure 7, reproduced as Fig 2. A, below), which he relies on to support his view that a differential amplifier can only amplify EMG signals. *See* Dyro Report at ¶ 65. However, the circuit of Dyro's Figure 7 is designed for the *express purpose of amplifying*, not removing EMG signals. This is exactly the opposite purpose of the '753 patent which seeks to substantially *reduce* EMG.

29. I have reproduced below Dyro's Fig. 7, labeled as Fig. 1A, and created my own modified version as Fig. 1B for illustrative purposes. The purpose of the device in Fig. 1A is to amplify the difference between EMGs detected at m1 and m2. To do this, the author identifies the placement of the reference electrode on electrically "unrelated tissue". Because the tissue is unrelated, it will not carry any signals related to m1 and m2, but it will carry environmental noise common to the noise in EMG1 and EMG2. As discussed earlier, the differential amplifier will substantially cancel this common noise, and will only amplify the differential EMG signal (*i.e.*, m1 –m2).

Fig. 1A

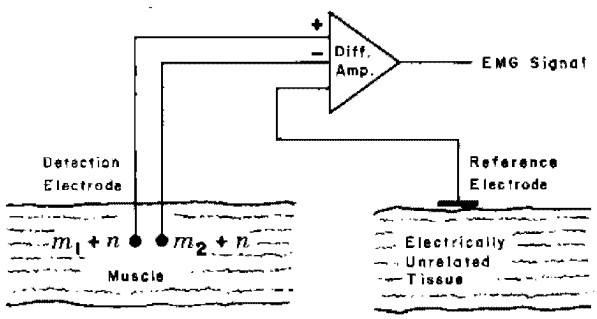
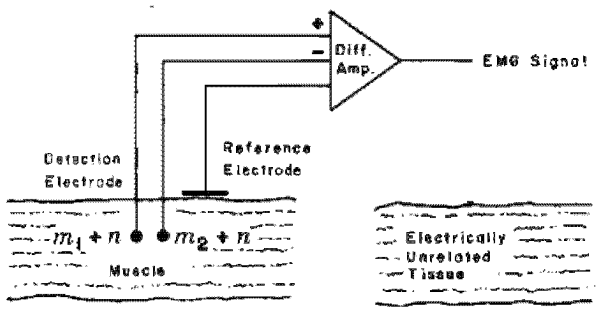


Fig. 1B



30. In contrast, the invention of the '753 patent places reference electrodes in close proximity to the signal electrodes on electrically "related tissue". Note that in Fig. 1 of the '753 patent, closely spaced signal and reference electrodes are gripped by the same hand (*i.e.*, electrically related tissue). As a result, the reference and signal electrodes will have a large common component (*i.e.*, common EMG), and that commonality will be treated as noise, substantially eliminated by the differential amplifier.

31. For Dr. Dyro's analysis to even begin to be pertinent, he would have had to consider the significance of the placement of the reference electrode in his Figure 7, and how the signal processing would change if the reference electrode were moved closer to the signal electrodes, such as I indicate in my modification to Dyro's Figure 7, in Figure 1B.

32. As can be seen in Fig. 1A, the author was attempting to reduce what is known as "cross talk" between the reference electrode and the biosignal electrodes. All of the applications that Dr. Dyro considered, like Fig 1A above, presumed the absence of cross talk between the reference electrodes and between the signal electrodes themselves. With the invention however, both of these types of cross talk are present (*i.e.*, because the contact electrodes are closely spaced on electrically related tissue, and because the common electrodes electrically link the two

hands.). The role of reference signals in designing circuits is well known in the field of biosignal acquisition. *See, e.g.*, Appendix 7, Column 1, ll. 30-65.

1. ECG Characteristics

33. The heart achieves its pumping action by rapid and synchronized depolarization starting in the atria (SA node) and spreading to the ventricles (via highly compact and conductive fibers). Because the heart is not aligned in the center of the body and has a tilt leftward from apex to bottom, ECG potentials have opposite polarity, when observed on opposite sides of a line tilted from left shoulder to right thorax/waist Appendix 8. Thus, ECG signals will have opposite polarity in the two hands.

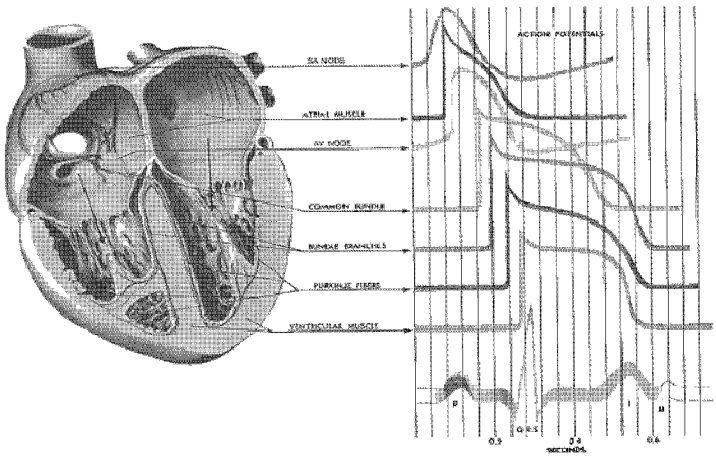


Figure 4.14 Representative electric activity from various regions of the heart The bottom trace is a scalar ECG, which has a typical QRS amplitude of 1–3 mV. (© Copyright 1969 CIBA Pharmaceutical Company, Division of CIBA-GEIGY Corp. Reproduced, with permission, from *The Ciba Collection of Medical Illustrations*, by Frank H. Netter, M.D. All rights reserved.)

Figure 2: Spreading wave of activation in the heart, and association with peaks in the ECG. Lower ECG trace is contaminated by 60Hz power line noise.

34. Depending on the site, ECGs measured with surface electrodes will have amplitudes ranging from 1 mV to 10mV with a bandwidth of 0.05-100Hz for standard 12-lead ECG Appendix 9.

35. A schematic of the portions of an ECG wave from (www.wikipedia.org/wiki/EKG) is accurate and is contained in Appendix 10 , reproduced below. Every beat of the heart emits an electrical pulse causing a wave pattern known as an electrocardiogram (ECG) wave. Conventionally, the different portions of the ECG wave are identified by letters, as shown below. The figure below illustrates the key phases of an ECG waveform, labeled as the P, QRS and T waves: these components are related to the state of activation in different parts of the heart, and are an integral part of the ECG, as opposed to noise.

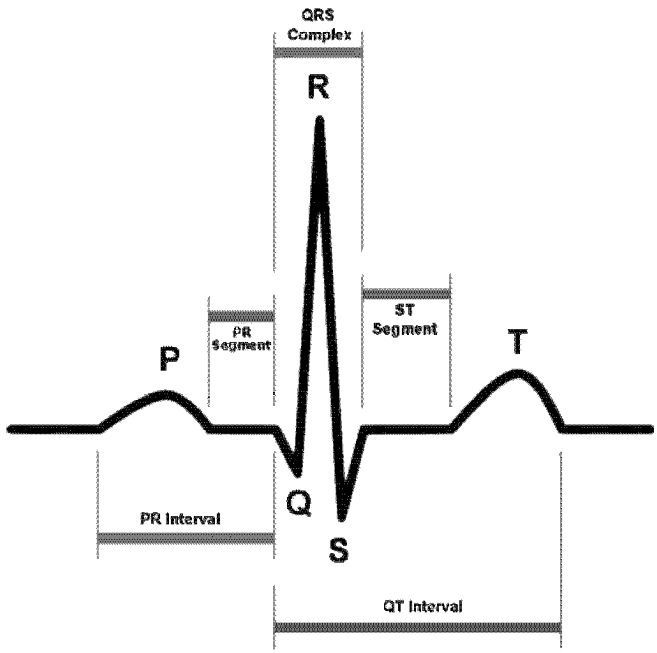


Fig. 3

The entire waveform is not needed to achieve high accuracy in all ECG applications. For example for simple monitoring of heart rate or pulse rate, only the "R" peak of the QRS complex is needed, since each R peak corresponds to one heart beat. Therefore, and as noted in the literature, while clinical applications require high fidelity in the range of 0.05-100 Hz, and intensive care units use devices with a fidelity of 0.50 - 50 Hz , a typical heart rate monitor only passes frequencies around 17 Hz with a strong resonance peak (Q factor). Appendix 11 [citing

Tompkins 1993]. In other words, heart rate monitors ignore most of the heart rate signal other than an area around the peak of the R wave.

36. All skeletal muscles, including hand muscles, emit their own electrical signals known as electromyograms (EMGs). As Figure 4 below illustrates, the EMG signal (red) can completely mask the peak of the R wave (black), making it difficult to differentiate the R wave peaks from the EMG noise.

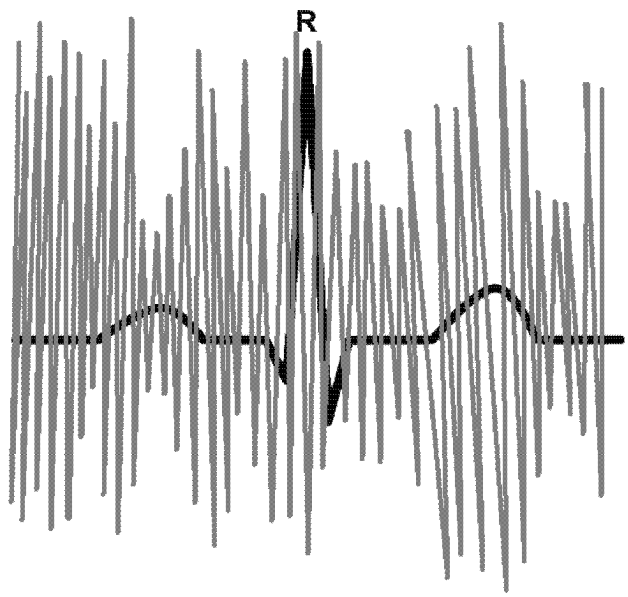


Fig. 4

The significance of noise in an electronic signal is defined in terms of the signal under measurement. In Figure 4 above, since the EMG noise masks the ECG signal under measurement, the noise is considered significant. When EMG noise is so much lower than the R-wave peaks that the noise does not interfere with the ability of a circuit to detect the R wave peaks, persons in the art commonly refer to the noise as "substantially zero."

2. Mathematical Simulation Demonstrating That Cross Talk Enables EMG Elimination

37. Dr. Dyro expresses an incomplete understanding of the nature of stochastic signals as they pertain to EMG. He does not believe that it would ever be possible to eliminate

an EMG noise using a differential amplifier. My testing of a circuit constructed in accordance with the '753 sufficiently demonstrates otherwise. *See infra.* I have also used a mathematical simulation program (MATLAB) widely accepted by persons of ordinary skill in the art to demonstrate that even when two signals are completely random at their sources, cross talk between the signals at the electrode level will enable a differential amplifier to substantially cancel the noise (EMG).

38. As illustrated in Figure 5 below, I generated two uncorrelated random signals filtered to 300 Hz to emulate the bandwidth that characterizes EMG signals detected by surface electrodes. I label these two signals Surface EMG1 and Surface EMG2, below, and assume first that there is no crosstalk between the electrodes' signals. Within each of EMG1 and EMG2, I embedded small pulses of opposite polarity, simulating an R wave pulse. As illustrated below (Figure 5), these small pulses are completely masked by the random noise in Surface EMG1 and Surface EMG2, consistent with Figure 4. The two signals are then processed by a differential amplifier, and the output appears in the bottom panel. As is evident, the differential amplifier simulation was unable to extract the pulse.

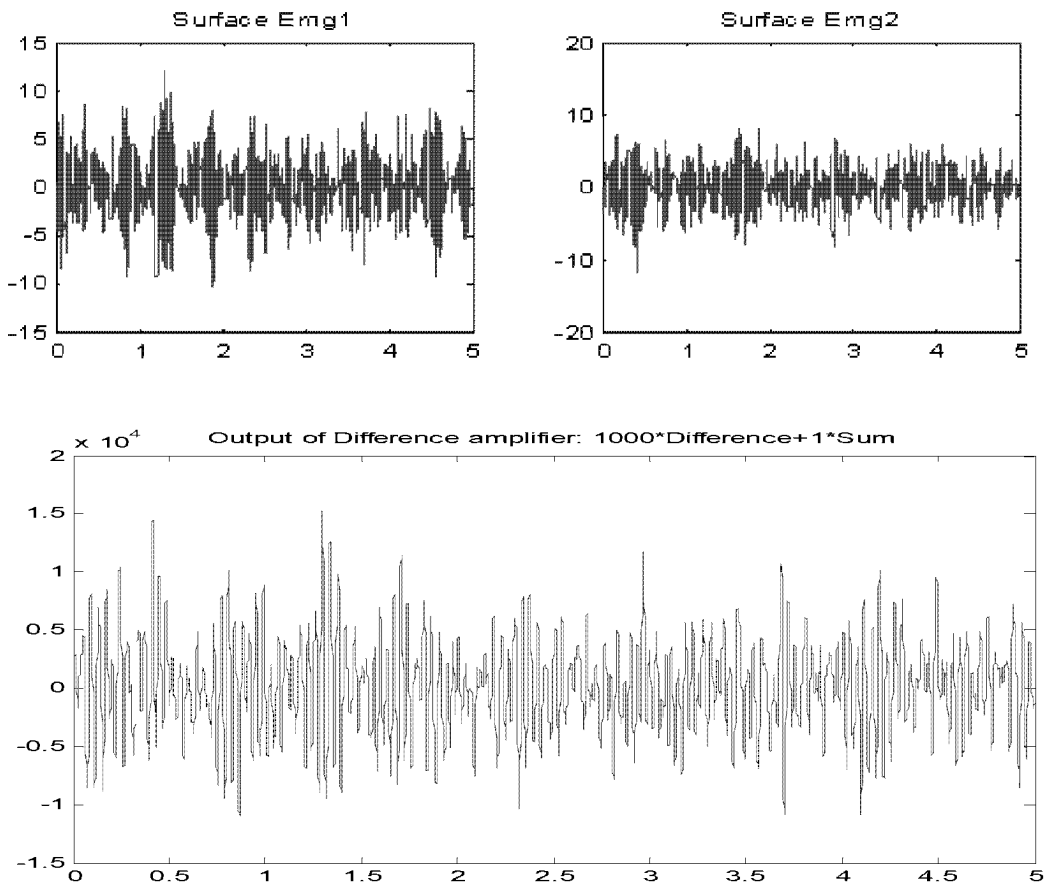


Figure 5: Two random signals with no correlation and no cross talk are not eliminated by a differential amplifier.

39. Subsequently, the same uncorrelated Signal EMG1 and Signal EMG2 were processed to simulate the cross talk that would occur if surface electrodes measuring them were placed next to each other. As can be seen in Figure 6 below, the presence of cross talk is not readily detectable by visual inspection of the surface EMG signals - they still appear as random noise. However, this time, the differential amplifier simulation easily reduces the background EMG noise to reveal the previously hidden simulated R wave spike.

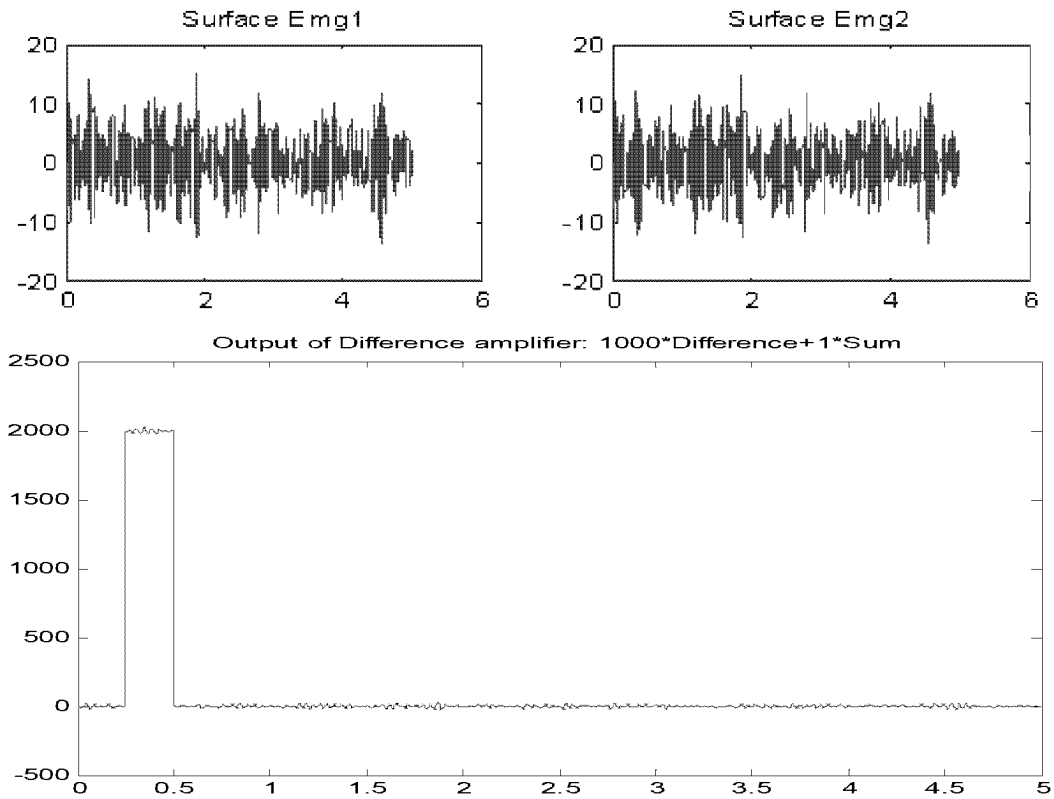


Figure 6: When two random signals have a significant component of correlation (cross-talk), the differential amplifier now can amplify and unmask a small pulse that was imbed in them with opposite sign, while rejecting the large noise levels seen in the top panels. (The same pulse was imbedded in Figure 5, but remained unseen).

40. Thus, Dr. Dyro's untested expectation that two EMG signals will always be amplified by a differential amplifier is wrong.

3. Other Factors Affecting Correlation between Detected EMG's

41. While the simulations in Figures 5 and 6 above assumed absolutely no correlation between the tissue *sources*, and assumed complete randomness as a worst case scenario, in the real world, EMG signal sources are neither completely random nor completely uncorrelated. Appendix 18, p.24-26; Appendix 19, p. 390

42. Depending on its physical characteristics, a contact sensor grasped by a user simultaneously receives an aggregate of many electrical signals emitted from many muscle fibers

beneath the skin in the range of the contact sensor, in a 3D volume. Thus, the contact sensor performs averaging that reduces randomness (low bandwidth noise has some autocorrelation).

43. In addition, if, as is illustrated in the '753 patent, contact sensors are located close together on electrically related tissue, there is cross talk between the sensors, as discussed earlier in this report, because their accessible 3D volumes overlap. Further, because the human body is a volume conductor, any two sites on the body where EMG is measured may also exhibit some component of co-modulation (common signal components) as the result of receiving similar motor neural drives from the brain (Appendix 12; see also any classical textbook on Neuroscience such as Kandel & Schwartz), and as the result of signal transmission between the electrodes through the conductance of tissue and skin. (Appendix 17).

44. Additionally there is the contribution of reflex loops and shared motor commands from the CNS and spinal cord in particular tasks (*e.g.*, gripping with both hands in the context of '753 patent). As a result of the brain's bilateral symmetry in movement control, when EMG is symmetrically detected on opposite sides of the body during a task that requires bilateral contraction of symmetrically disposed muscle groups, those EMG signals will exhibit an increased synchrony in their timing (phase) and activation (amplitude) levels because they share a motoneural drive supported by symmetrical premotor circuits in the spinal cord. (Appendix 12 and Appendix 13).

45. It has also been demonstrated by early simulations that increased muscle fiber recruitment, associated with summation of a larger number of activation impulses under an electrode, can cause an increase in the probability of synchronous fiber activations and with it an increase in the EMG amplitude detected at the surface. Yet, little change in the dominant frequency of activity will be associated with the increased power in the EMG. (Appendix 13).

So co-activation of muscle groups in a limb or across limbs is likely to also increase the common component in their EMG signals.

46. All the above comments are in the context of traditional EMG techniques, using two surface electrodes for each muscle, a separate differential amplifier for each EMG channel, and a shared reference on *unrelated* tissue. However when implementing the disclosure of the '753 patent, the reference is *deliberately* shared not only on related tissue, but also between the hands via a common reference connection. As a result, there will be even greater commonality beyond that which occurs through natural phenomena.

4. Bioamplifiers- Design in Presence of Biosignal Interactions

47. Someone of ordinary skill in the art of biosignal acquisition would recognize differential amplifier 23 in the '753 patent as a bioamplifier. Indeed, Dr. Dyro acknowledged the same in his deposition. (Appendix 14 at p. 123).

48. In 1992, a person of ordinary skill in the art of biosignal acquisition would have known that a bioamplifier contains three stages for the detection of a desired signal: a differential amplifier to improve the saliency of a desired signal above the 'noise' (read unwanted) signals, a band-pass filter that removes unwanted low-frequencies caused by such factors as electrode drift and high frequencies not related to the signals of interest, and a final additional amplification of the 'clean' signal to levels required by the monitoring device and application. (Appendix 15).

49. In the context of the '753 patent, the desired signal is the ECG, specifically the rate of occurrence of the peak of the "R" wave. The unwanted signals include the 60Hz electrical noise, and muscle EMGs that can vary with movement. It would be reasonable for one skilled in the art to select the first stage of an instrumentation amplifier with bandwidth of about at least 1 kHz, to pass all of the EKG waveform, and allow proper rejection of common signals in the bandwidth of undesired EMG signals (up to at least 500 Hz with surface electrodes). A

second stage would further filter and amplify the result to restrict the signal to the EKG bandwidth (e.g., .05-100 Hz), and remove any electrode drift, and residual electrical noise and residual EMG above this bandwidth. The final stage varies with the application, and in the case of pulse rate detection would apply a band pass filter to isolate the peak of the R wave (*e.g.*, centered around about 17 Hz). In the case of the '753 patent, the last two stages can be applied simultaneously, with a bandpass filter depicted in the patent Fig. 2.

5. Implementation of invention as described in '753 Patent

50. With the invention of the '753 patent, the common electrodes of opposite hands are connected to a single common potential. (Appendix 1 at col 5, ll. 34-36). With this arrangement, I found that the detected EMG from the two live electrodes must have substantially the same magnitude and phase, since a substantially zero EMG component appeared in the output of the difference amplifier. (*i.e.*, A difference amplifier subtracts signals that are substantially the same, thereby removing unwanted signals. Thus, to determine the similarity of input signals, one need only look to a difference amplifier's output. Since a difference amplifier reduces to substantially zero input signals that are of substantially equal magnitude and phase, my observation of substantially zero EMG signal at the output of the difference amplifier definitively establishes that the input EMG signals were of substantially equal magnitude and phase.) On the other hand, the output of the difference amplifier produces an amplified ECG signal, confirming that the ECG detected by the two live electrodes was in phase and of opposite polarity. I disagree with Dr. Dyro's assertion that claim 1's reference to 2 EMGs with "substantially equal magnitude and phase" requires any particular percentage of similarity. I saw no such support for that assertion in the references he sites. The proper interpretation of that term, as would be understood by one of ordinary skill in the art, is that the signals should be

similar enough to achieve a substantially zero EMG output, as described in paragraph 36 of this Report.

51. I demonstrated the foregoing principles using an electrical circuit corresponding to the one illustrated in Figures 1 and 2 of the '753 patent, which I recognize as an indication in the patent as how to make the invention work. Construction of this working model involved parts and miscellaneous materials available in our lab, costing less than $50, excluding the available power sources and oscilloscope. The focus was on the first stage of the patent diagram in Figures 1 and 2, since that is the part deemed to be unworkable by Dr. Dyro. Specifically, I tested the electrical circuit depicted in Appendix 16 to this report, and reproduced results in the photographs of Figure 7, below.

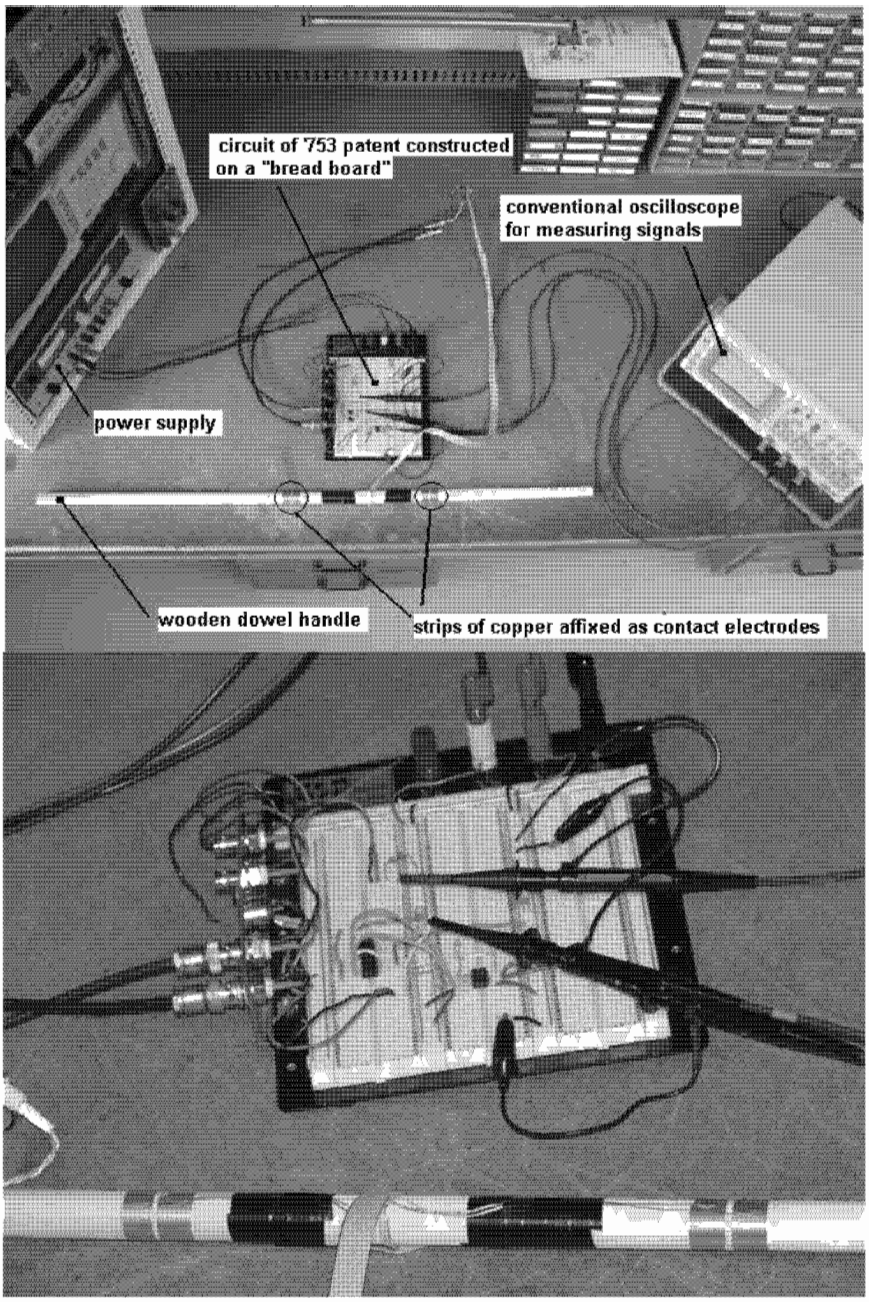


Figure 7: Photographs of the 'breadboard' implementation of the `753 patent, including a simple dowel arrangement for the 4 copper electrodes held by the two hands. The circuit was limited to that part of Figure 2 in the patent representing electrode connections and the instrumentation (difference) amplifier.

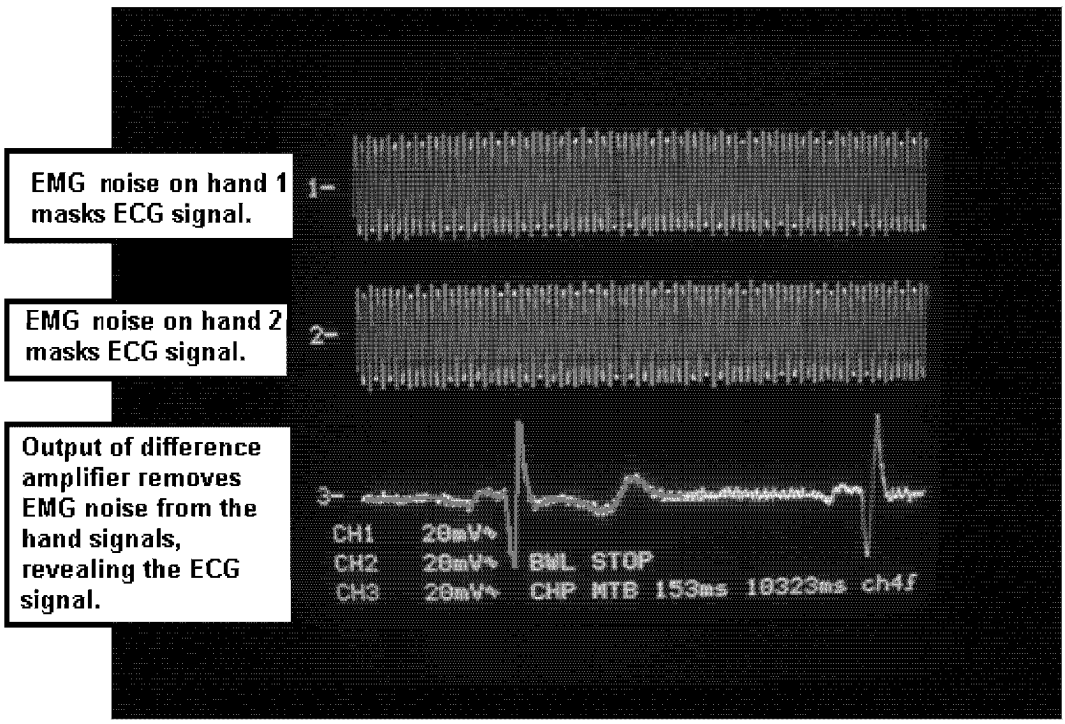
52. The above-illustrated apparatus (Figure 7) was built by my lab assistant, at my direction. Specifically, I handed him Figures 1 and 2 of the '753 patent, and asked him to build the invention. Using a 7/8 inch broomstick-like wooden dowel, wire, copper foil, glue, and

electrical tape, all found in our lab, he constructed the handle with wired contact electrodes, as illustrated above. He constructed the circuit using off-the-shelf components plugged into a conventional "bread board", all of which are common items found in our lab, and commonly available on the market. He then connected the circuit to an oscilloscope to enable me to monitor measured signals. He completed all this work in about two hours. I tested the invention immediately thereafter, and without any adjustment or revision, the apparatus worked just as described in the '753 patent.

53. While the circuit is unique to the extent I have not seen reference to it before working on this case, the construction of the circuit itself is quite simple. The pertinent portion of the circuit recited in claim 1 of the '753 patent is straightforward, requiring a single difference amplifier wired to four contacts on a handle. Based on my experience working with students and persons of ordinary skill in the art over the last 25 years, I have no doubt that using the '753 patent as a guide, the circuit could have been built within a matter of hours by a person of ordinary skill in the art in 1992, and without any significant experimentation.

54. Just as is illustrated in Figure 2 of the '753 patent, the electrical circuit that I tested includes an elongate member with four contact sensors (two for each hand). One outer contact sensor for each hand was connected to an input of the difference amplifier. The two internal contacts from the two hands were connected to a point of common potential, as illustrated in Figure 2 of the patent. A three channel oscilloscope was connected to both the inputs and the output of the differential amplifier for comparison purposes. An actual image of the oscilloscope traces in Figure 8 below demonstrates operation of the invention. (red markings added for discussion purposes). These traces reflect normal operation of the circuit under normal conditions (with external noise controlled to ensure an unbiased analysis).

Figure 8: Inputs & Output of differential amplifier in the '753 patent

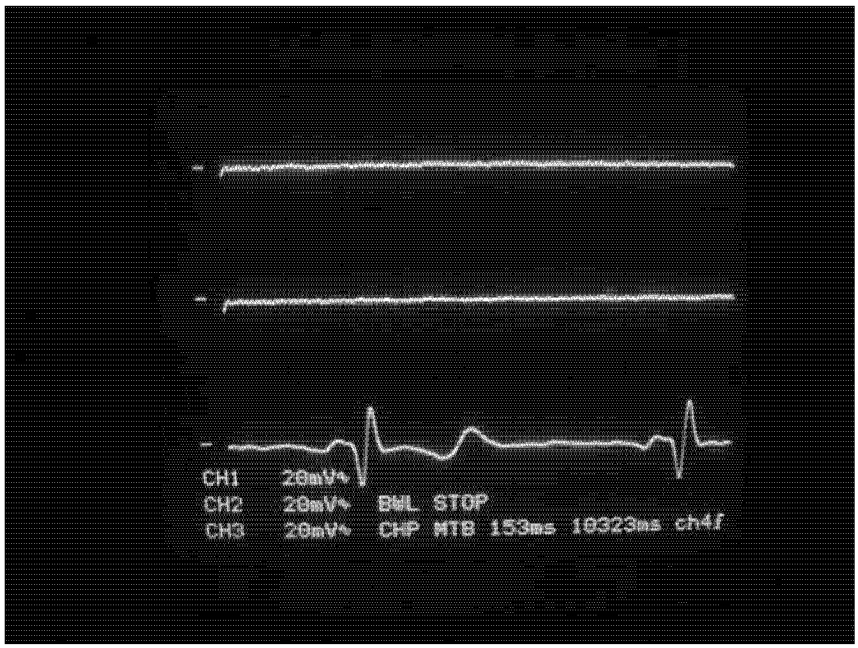


55. Signals 1 and 2 (*i.e.*, the top two traces identified by the numerals 1 and 2 at the left side of the screen) contain the combined ECG, EMG, and ambient noise from right and left hands (outer electrodes) before the signals enter the differential amplifier. As can be seen, the first and second signals appear to be random noise. It is impossible to discern an ECG signal from either of the right and left hand contact sensor signals. The same is not true of the third signal at the *output* of the differential amplifier. In the third trace, the differential amplifier outputs an ECG signal containing substantially no EMG noise. This is the result of the differential amplifier canceling the EMG noise and amplifying the ECG signal just as described in the '753 patent. A depiction of a clean ECG signal (superimposed as a red reference wave), demonstrates how little noise actually remains (the green bleeding above and below the red reference wave demonstrates the inconsequential amount of residual noise). The residual EMG noise is so negligible compared to the ECG signal under measurement that EMG does not

interfere at all with the ability to detect the peaks of the R waves. As a result, the residual EMG noise is referred to in the art as being "substantially zero."

56. In addition, in 1992, many electrical engineers were still using analog oscilloscopes in which a "flying dot" moved across the screen without leaving a trace. When that common oscilloscope is used, it is much more difficult to visually detect small deviations from an expected trajectory. Because the EMG signal is reduced to substantially zero by the invention, a person of ordinary skill in the art in 1992 viewing a "flying dot" on an analog oscilloscope would have had a difficult time discerning appreciable deviation from the expected ECG signal, and would have characterized the EMG as substantially zero. Moreover, a person of ordinary skill in the art in 1992, implementing the patent, would have understood the difference amplifier depicted by reference numeral 23 in Figure 2 to be a bioamplifier, which by definition, includes filtering to isolate the signal of interest, *i.e.*, the ECG signal (¶¶ 46-47, *supra;* Appendix 14 at p. 207-08). As a matter of elementary biosignal processing, it is known that the bandwidth of an ECG signal does not typically extend beyond 150 Hz, while that of an EMG signal can reach over 1000 Hz., and for heart rate applications, the bandwidth can be as low as 20Hz (*see* ¶¶ 44-45, *supra*). As a result, a person of skill in the art attempting to enhance an ECG for purposes of counting heartbeats, would choose a bioamplifier configured for ECG amplification (*e.g.*, including built-in filtering to restrict the bandwidth to that of the ECG and amplify as needed.) When such filtering is applied, as is illustrated in the following traces in Figure 9, below, the substantially zero EMG approaches absolute zero. (The undulations in the third trace below are part of the ECG signal, not EMG).

Figure 9: Effect of Bioamplifier Filtering



Because the circuit was built in rough fashion on a "bread board", I expect the residual noise in the traces illustrated above and in paragraph 54 to be higher than if built in a more permanent manner on a printed circuit board. The ability of even a rough circuit to cancel EMG to the level illustrated in the above traces demonstrates the effectiveness of the underlying principles of the invention.

57. In order to verify that the noise cancellation was not all attributable to 60Hz interference, I took the measurements of Figures 8 and 9 in a 'shielded' room at a nearby hospital. Such a room is surrounded by a copper mesh in the floor, walls, and ceiling, to block electromagnetic interference. Hence, in this case, the recorded input signals to the differential amplifier would be dominated by EMG activity. The output 'cancels' substantially the EMGs and highlights the desired ECG.

58. In any case, even at the immediate output of the differential amplifier before any filtering, the first oscilloscope image above demonstrates substantial elimination (reduction to

zero) of unwanted EMG signals from the hands, leaving a clear ECG signal. I tested the circuit many times, and the traces above are generally reflective of my repeated testing. I also experimented with the circuit to see how changes might affect performance. When a reference point was chosen other than on related tissue, the output of the differential amplifier was noisy and ECG R waves were not readily discernable. The same result occurred when the two hands were not connected to a common reference point.

59. The device described in the '753 patent achieves the desired goal and is fully functional: it substantially reduces to zero the EMG signals from the hands, while amplifying the desired ECG signals.

60. Based on my experience in the field for over 20 years, my knowledge of the level of ordinary knowledge in the art, my review of the '753 patent, and my circuit testing and mathematical modeling as detailed in the preceding paragraphs of this report, I have no doubt that 1) the '753 patent describes an operative invention; 2) the description in the '753 patent is sufficiently detailed to have been fully understood by a person of ordinary skill in the art in 1992; and 3) the patent's description would have enabled a person of ordinary skill in the art in 1992 to make the invention in a matter of hours without significant experimentation required.

IV. DR. DYRO'S CONCLUSIONS ARE NOT SCIENTIFICALLY SOUND

61. I carefully considered Dr. Dyro's Report and reviewed all of the exhibits he relied upon. The exhibits he cites do not support his conclusions. There is no document in his report that even remotely suggest that if common electrodes on two hands are connected to a common source of potential that amplitude and phase of EMG signals from those two hands will not be correlated, enabling cancellation using a differential amplifier.

62. Dr. Dyro cites no reference for purposes of discussing the effects of connecting common electrodes on two hands to a point of common potential, despite that it is a feature of the '753 patent.

63. Dr. Dyro cites no reference for purposes of discussing the effects placing signal electrode and reference electrode on electrically related tissue, despite that it is a feature of the '753 patent.

64. I attended Dr. Dyro's deposition and heard him testify that he did not consider the effect of this common connection (Appendix 14 at p. 193), and did not consider the effect of placing the common and live electrodes on electrically related tissue. (Appendix 14 at p. 248). My testing demonstrates that these features have a significant impact on the signal out of the differential amplifier, and Dr. Dyro's failure to consider these features of the patent render his opinion unscientific and unreliable.

65. Moreover, sound engineering principles would require an engineer asked to evaluate the operability of a circuit-based device (such as described in the '753 patent) to first test the circuit before rendering opinions, particularly in this case where the circuit's construction is quite simple enabling it to be built in a matter of hours with off-the-shelf parts. His failure to test is a departure from my understanding of accepted engineering practice.

66. There is no scientifically accepted methodology associated with the incorrect conclusion in Dr. Dyro's report that it is impossible to cause EMG signals to have substantially equal amplitudes and phase when the wiring of Figure 2 of the patent is followed, nor is there any scientifically accepted methodology in his report to support his incorrect conclusion that with the wiring illustrated in the patent, a substantially zero EMG signal can not be output from a difference amplifier.

67. I do not believe that the methodology of Dr. Dyro's report would be considered sound in the scientific community. It is not based on sufficient facts or data and it is not the product of reliable principles or methods. Rather, it is a statement of theoretical extrapolation not supported by the documents cited. It is purely speculative in its conclusions about how the invention of the patent would work, and is not grounded in science. Even when Dr. Dyro speculated in his deposition that the output of the differential amplifier in Figure 2 of the '753 patent would amplify EMG, he was completely wrong, as my testing outlined in this report demonstrates.

V. MISCELLANEOUS

68. I am being compensated for my work on this matter at a rate of $400 per hour for all work I perform other than testifying. My compensation for testifying is $700 per hour. My compensation is not based on the outcome of this matter.

69. I reserve the right to amend or supplement this report based on further preparation in this action, including my review of any expert reports, expert testimony or any other reports and evidence submitted on behalf of Nautilus.

70. Attached hereto are true and correct copies of the Appendix references cited in this Report.

I make this declaration under penalty of perjury of the laws of the United States.

Dated: September 19, 2008

H L Galiana

Henrietta Galiana, Ph.D

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Appendix 5	Cooper, R., Osselton, J.W. & Shaw, J.C., *EEG Technology*, Butterworths/London, 3d ed., 1980., pp. 125-126
Appendix 6	Meiksin Z.H. & Thackray, P.C., *Electronic design with off-the-shelf integrated circuits,* 2d ed., Prentice Hall, 1984, pp. 22-23.
Appendix 7	US Patent No. 4,432,369, col. 1, ll. 30-65
Appendix 8	Webster J.G. (ed.), *Medical Instrumentation- Application and Design*, 2d. ed., Chapter 4, The origin of biopotentials (J.W. Clark), Houghton Mifflin, 1992, Fig. 6.1, p. 276 and Fig. 4.14, p. 166
Appendix 9	Bronzino J.D. (ed. in chief), *The Biomedical Engineering Handbook*, Chapter 54, Biomedical Signals (B. Onaral), CRC Press, 1995, Table 54.1, p. 808
Appendix 10	A schematic of the portions of an ECG wave from www.wikipedia.org/wiki/EKG
Appendix 11	Tenedero, Christopher M., Raya, Mary Anne D., & Sison, Luis G. Ph.D. *Design and Implementation of a Single-Channel ECG Amplifier with DSP Post-processing in Matlab*, 1997
Appendix 12	Galiana H.L., Neural Network Symmetry Supports Sensory Fusion and Motor Coordination, *Proc.* 1st *Int. IEEE EMBS Conference on Neural Engineering,* Capri, Italy, March 20-22, 2003, pp. 422-425
Appendix 13	Basmajian J.V., *Muscles Alive - Their function revealed by electromyography*, 2d. ed., Williams & Wilkins, 1967, pp. 58-60
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Appendix 17	Plonsey R., *Quantitative formulations of electrophysiological sources of potential fields in volume conductors*, IEEE TBME 31: 868-871, 1984. (Ex. C from Dyro Report)
Appendix 18	US Dept of Health and Human Service, CDC, *Selected topics in surface electromyography for use in the occupational setting: Expert Perspectives*, March 1992, pp. 24-26
Appendix 19	Rossignol S., *Startle Responses recorded in the leg of man*, Electroencephalography & Clin. Neurophysiol., Vol 39, 389-397, 1975